

Reference Manual

H-TRONplus



INSULIN PUMP

 **DISETRONIC**
MY CHOICE

Dear H-TRONplus pump user,

Congratulations on your new H-TRONplus Insulin Pump. You and your H-TRONplus Insulin Pump are unique. Therefore, it is important that you or your health care team fill in the following information.

Type of device H-TRONplus
Serial-number _____

Insulin (name/type) _____ U-100

Training Place _____
Date(s) _____
Trainer _____

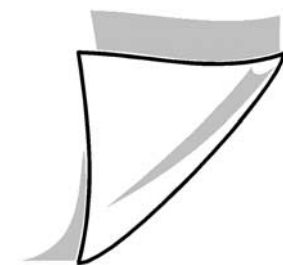
Useful addresses Your contact for medical emergency and/or information about the therapy (Doctor/health care provider)

Phone _____

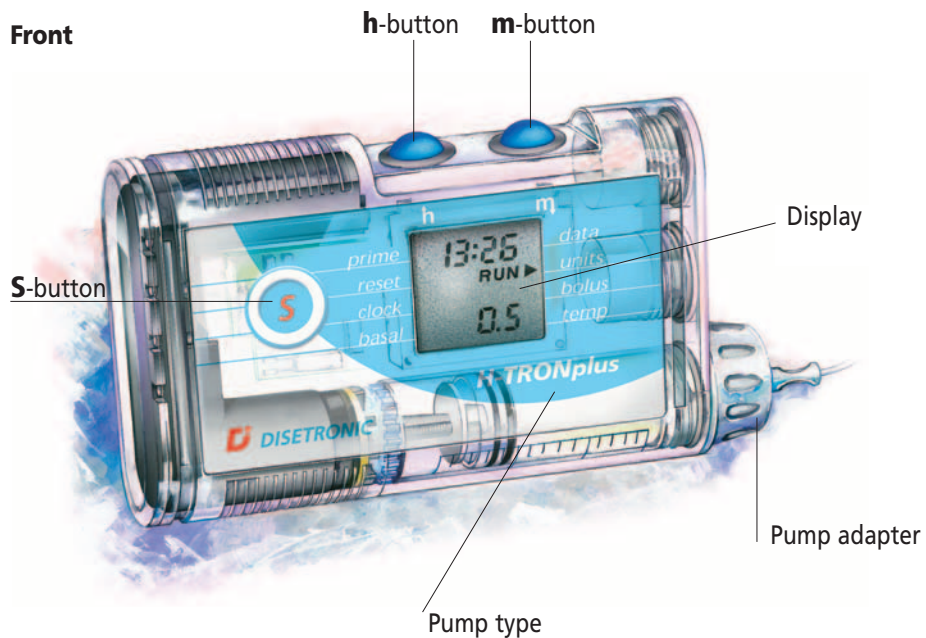
Your contact for assistance with and/or additional information about the H-TRONplus Insulin Pump

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Toll free 1 800 280 7801
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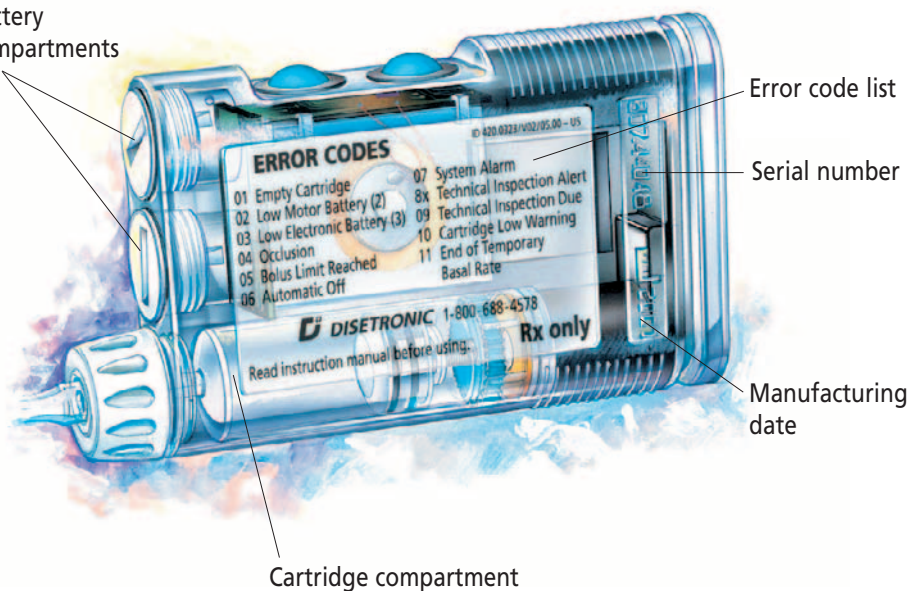


Front

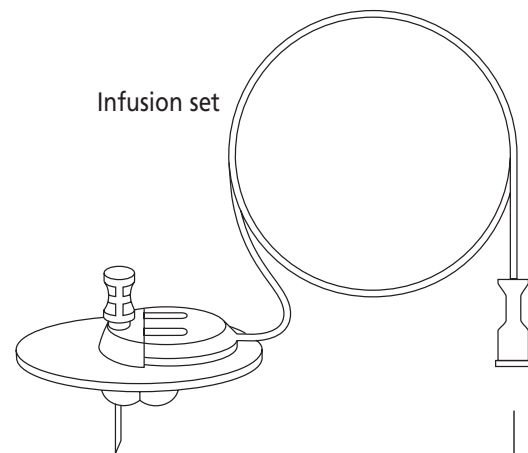


Back

Battery compartments

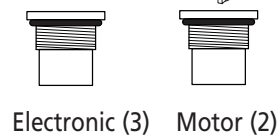


Infusion set



Battery tool

Batteries

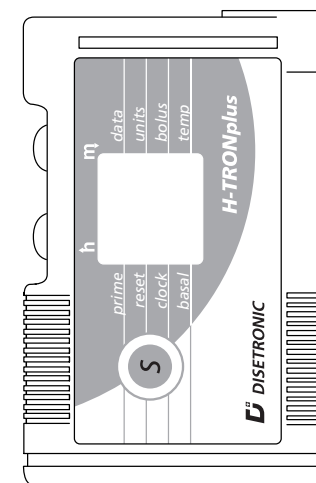


Cartridge

Pump adapter

Cartridge plunger

Piston rod



ERROR CODES

ID 420.0545/V03/03.01

- | | |
|-------------------------------|--------------------------------|
| 01 Empty Cartridge | 07 System Alarm |
| 02 Low Motor Battery (2) | 08 Technical Inspection Alert |
| 03 Low Electronic Battery (3) | 09 Technical Inspection Due |
| 04 Occlusion | 10 Cartridge Low Warning |
| 05 Bolus Limit Reached | 11 End of Temporary Basal Rate |
| 06 Automatic Off | |

DISETRONIC 1-800-688-4578

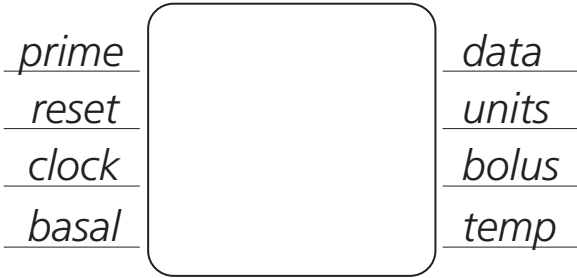
Read instruction manual before using.

Rx only

Short explanation of the error code list shown on the back of the H-TRONplus Insulin Pump.

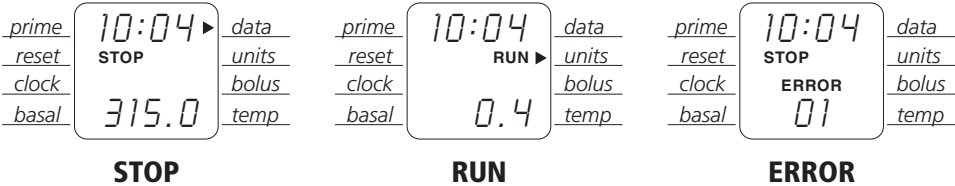
Always refer to the detailed instructions concerning "Alarms (ERROR)" in section 7.

Programming symbols



Symbol	Meaning	Page
<u>prime</u>	prime the infusion set	42
<u>reset</u>	reset a new cartridge	41
<u>clock</u>	set the time, control the beeps	27, 55
<u>basal</u>	program and check the basal rate	28
<u>data</u>	insulin remaining, recall data memory	50, 49
<u>units</u>	current basal rate	29, 45
<u>bolus</u>	bolus	46
<u>temp</u>	temporary basal rate change	52

Quick Look at the Operating Displays



Short explanation of the error codes

ERROR CODES

ID 420.0545/V03/03.01

01 Empty Cartridge	07 System Alarm
02 Low Motor Battery (2)	8x Technical Inspection Alert
03 Low Electronic Battery (3)	09 Technical Inspection Due
04 Occlusion	10 Cartridge Low Warning
05 Bolus Limit Reached	11 End of Temporary Basal Rate
06 Automatic Off	

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Read instruction manual before using.

Rx only

Short explanation of the error code list shown on the back of the H-TRONplus Insulin Pump.

Always refer to the detailed instructions concerning "Alarms (ERROR)" in section 7.

No.	Meaning of the ERROR	What you have to do	Page
01	Empty Cartridge	Silence alarm. Insert new cartridge. Change infusion set.	60
02	Low Motor Battery (2)	Silence alarm. Replace motor battery.	60
03	Low Electronic Battery (3)	Silence alarm. Replace electronic battery.	61
04	Occlusion	Silence alarm. Check blood glucose value. Change infusion set, or check piston rod, or check pump.	62
05	Bolus Limit Reached	Silence alarm. See manual.	65
06	Automatic Off	Silence alarm. See manual.	66
07	System Alarm	Remove batteries. Press S for three seconds. Reinsert batteries, set clock, check basal rates.	67
8X	Technical Inspection Alert	Silence alarm. Schedule technical inspection.	68
09	Technical Inspection Due	Silence alarm. Schedule technical inspection. Begin alternate insulin delivery method.	69
10	Cartridge Low Warning	Silence alarm. Insert new cartridge soon.	70
11	End of Temporary Basal Rate	Silence alarm.	71



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Explanation of the symbols and markings

safety instruction:



See instructions in the reference manual.

CE 0123

Marking of conformity according to the European Medical Device Directive MDD 93/42/EEC with the number of the notified body (0123).

IPX7

Pump case protects the pump against the effects of temporary immersion in water according to the standard IEC 60529. Protection only if pump case is not damaged and the batteries are properly inserted.



Warning: Avoid any contact of the pump with water.



Electronic device of type BF according to the standard IEC 60601-1. Protection against electric shock.

Meaning of the safety symbols



Warning: Disregarding this warning may seriously harm your health or cause a defect of the device and/or its accessories.



Caution: Disregarding this safety instruction may harm your health or cause a malfunction of the device and/or its accessories.

In section 11 (Technical data), under 11.2, is a list of additional symbols of the pump and the accessories.

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... H-TRONplus Insulin Pump

Read this manual carefully before using the H-TRONplus Insulin Pump. Always refer to this manual for questions about operating and troubleshooting the pump.

User manual

This user manual is written for users of the H-TRONplus Insulin Pump as well as health care professionals. The user manual is designed to provide you with the necessary information for safe and efficient use of the H-TRONplus Insulin Pump.

Please refer to the instructions for use of the accessories and disposable materials needed to operate the H-TRONplus Insulin Pump.

For any further information please contact Disetronic.

Intended use of the H-TRONplus Insulin Pump

The H-TRONplus Insulin Pump is a prescription use only product and has been developed exclusively for the continuous subcutaneous delivery of U-100 insulin for the treatment of insulin-dependent diabetes mellitus. Do not use the H-TRONplus Insulin Pump for the administration of medications other than U-100 insulin. Do not modify the device in any way as this could lead to malfunction.

Continuous Subcutaneous Insulin Infusion (CSII) using the H-TRONplus Insulin Pump

You must be trained by your doctor and your health care team on insulin pump therapy as well as on the H-TRONplus Insulin Pump.

Do not operate the H-TRONplus Insulin Pump without knowing your personal settings. **The pump must be programmed with your personal settings prior to starting the therapy.**

This section includes:

1.1 Warnings

1.2 Precautions



Caution: Rx-only! The device is restricted to sale by or on the order of a licensed health care practitioner.

Prior to starting the pump be aware of the following warnings and precautions.

1.1 Warnings



Warning: Avoid any contact of the pump with **water**. Water entering the pump may result in a malfunction which could cause severe hypoglycemia (low blood glucose value) or complete pump shut-down.

Should your pump come into contact with water, check whether:

- Water has gotten inside the pump case, or whether water is visible in the display area.
- The cartridge contents expected agree with the insulin remaining counter on the display.

If you detect water in the pump casing or think the cartridge contents are inconsistent with what you expect, then put the pump in STOP immediately and take the following steps:

- Remove the infusion set from your body.
- Measure your blood glucose value and correct it, if necessary, per your doctor's orders.
- If you are unable to correct your blood glucose value, contact your health care provider immediately or get transportation to the nearest emergency room.
- If you are able to correct your blood glucose value, inspect the system, i.e. the pump, the adapter and the infusion set.

- If you detect a problem, follow the instructions for returning your pump and continue therapy with your back-up insulin delivery device.
- Call the toll-free number on the back of your pump for troubleshooting help or to make arrangements to return your H-TRONplus for inspection.

Always dry your pump with a dry cloth after accidental contact with water.

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.



Warning: Incorrect programming of the pump will lead to an incorrect dose of insulin. Do not operate the H-TRONplus Insulin Pump without knowing your personal settings. The pump must be programmed with your personal settings prior to starting the therapy! If you are not experienced, make sure that your doctor or health care professional checks your personal settings.

Frequent self-blood glucose monitoring will help you to find your personal settings more rapidly and to detect incorrect doses early. Successful pump therapy requires at least 4 measurements of blood glucose per day, or as directed by your health care team.

Since only fast-acting insulin is used for pump therapy, there is no insulin reserve in the body. Without insulin, diabetic ketoacidosis can develop rapidly, leading to hospitalization. If insulin delivery is interrupted for any reason, be prepared to replace the missed insulin immediately. Make sure to check your blood glucose regularly to determine if the system is functioning properly.



Warning: If an alarm "occlusion" **ERROR 04** appears, immediately check your blood glucose level, because delivery of insulin may have been interrupted. If blood glucose is high, treat according to your health care team's instructions.

An ERROR 04 may be caused by an empty cartridge, a reused cartridge, a blocked infusion set, a dirty or damaged piston rod or a low battery in compartment 2 (motor).



Warning: A leakage in the system is not detectable by the insulin pump. Therefore, check the cartridge, the infusion set and its connections regularly. Should you detect any loss of insulin, replace the leaking component.



Warning: Air bubbles in the cartridge and in the infusion set cause the infusion of air instead of insulin. Your body will not receive the required amount of insulin. An "occlusion" ERROR 04 may be delayed. Remove these bubbles while filling the cartridge and priming the infusion set.

Cold insulin may release dissolved air when warmed. Use only insulin at room or preferably body temperature when filling the cartridge and priming the infusion set. Check the system for air bubbles regularly and, if necessary, change system components according to the procedure described in the reference manual in section 4, "prepare the cartridge and attach the infusion set," or in section 5.4, "change a cartridge and an infusion set."



Warning: Never carry out the functions "program the basal rate," "change the cartridge" and "prime the infusion set" with an **infusion set inserted** into an infusion site in your body. Otherwise you risk uncontrolled delivery of insulin into your body. With disconnectable infusion sets, be sure you have disconnected prior to programming, changing, or priming. Always follow the instruction for use of the infusion set you are using.



Warning: Check for chips and cracks if the pump is dropped. Do not use the pump if it is chipped or cracked.

Inspect the pump daily for cracks or chips. Check around battery compartments. Also check the **h**-, **m**- and **S**-buttons for cracks or damage. Be sure that the buttons rebound when pressed. Avoid chips and cracks by safely attaching your pump to your body or to your clothes.

Be sure that you can safely protect the pump while engaging in any sports with rough body contact, like boxing, football, hockey or rugby. Otherwise, remove the pump.



Warning: Avoid **electromagnetic fields** of radar or antenna installations, of high-voltage lines, of power stations, of X-Ray sources, MRI, CAT scan or the like. Do not use the pump in these areas.

If this situation is unavoidable you must take off the pump beforehand. Otherwise electromagnetic fields can lead to defective functions in the pump's electronics and could result in "ERROR 07, System Alarm".

Because of the variety of portable phones, their influence on the pump cannot be ruled out completely. It is advised to keep the pump at a distance of at least 4 inches (10 cm) from the phone while the phone is in use.

Security systems for transit checks in airports as well as anti-theft monitoring devices installed in department stores, shops, etc. are harmless and do not affect the functioning of the insulin pump.

1.2 Precautions

Accessories and disposables



Caution: Only use **accessories and disposable materials** that are designed expressly for use with the pump. Other accessories and disposable materials may not have been checked for compatibility with the H-TRONplus Insulin Pump and may, therefore, endanger your health if used.

Always have extra accessories and disposable materials with you. This will allow you to exchange components when needed.

Batteries



Caution: Always have extra **batteries** available and pay attention to the following:

- Do not store the batteries in the refrigerator or freezer. High humidity affects battery life.
- Always keep batteries in the original package until ready to use. Prevent early discharge of the batteries by preventing contact between the batteries themselves and between the batteries and any other metal (coins, keys, etc.).
- For operating the pump, the temperature of the batteries must be +41°F to +122°F (+5°C to +50°C).
- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.
- To tighten batteries use only the Disetronic battery tool until the top of the battery is level with the pump case. Over tightening may cause pump case damage.

Sun and UV radiation and heat



Caution: Do not place the pump in direct sunlight. Overheating of the insulin and the pump must be avoided.



Caution: Temperatures **over 122°F** (50°C) may damage the insulin. Temperatures over 149°F (65°C) may also damage the electronics of the pump. Only use the H-TRONplus within its temperature limits.



Warning: Always remove your H-TRONplus before you enter a sauna, hot tub or a Jacuzzi. Do not use the pump in water!

Cold



Caution: Use of your pump at temperatures under 41°F (5°C) may cause a malfunction of the batteries. Wear your pump under your clothes or directly on your body in cold weather.

Variation of the air pressure



Caution: The pump adapter has two holes to allow the variation in air pressure within the cartridge compartment. **Never plug the two holes.** In this way a variation of the air pressure, for example in an airplane or when climbing on a mountain, does not affect the pump or the dosage of the insulin.

Control the beeps (special function)



Caution: The H-TRONplus allows users to silence warning beeps, confirmation beeps and beeps when buttons are pressed. The beeps caused by an alarm (ERROR-message) can not be silenced when the pump is in RUN. Check the display of the H-TRONplus Insulin Pump regularly, especially if for any reason you might be unable to hear the beeps (i.e. noise). This is the only way you will be aware of any changes in the pump in a timely manner.

Changing to another pump



Caution: Prior to use, always check the settings of a replacement, a spare, or a new pump, in order to avoid a wrong dosage.

Cleaning



Caution: Do not clean with water! Do not use any solvents or strong detergents for cleaning. Only use a soft dry cloth.

Cosmetics, soaps, lotions, deodorants



Caution: Avoid any contact of the infusion set and especially of the connecting parts of the pump with antiseptics, antibiotic creams, soaps, perfumes, deodorants, body lotions or any other cosmetics. They may cause damage to these parts.

Insurance



Your new insulin pump is an expensive medical device. We strongly encourage you to add your pump to your homeowner's insurance policy to protect you in case of accidental damage or loss. Ask your insurance agent for details.

Please keep these safety instructions in mind. For additional questions please contact your health care team and/or Disetronic.

For further recommendations for daily use, see section 9 (special situations).

This section includes:

2.1 Safety and warning installations of the H-TRONplus

2.2 Handling and display

2.3 Operating status (STOP/RUN)

2.4 Programmable settings

2.5 Accessories and disposables

The Disetronic H-TRONplus is a battery operated, microprocessor-controlled insulin pump. It is intended for subcutaneous infusion of insulin.

Please refer to the section 11 "Technical data" for additional technical information.

2.1 Safety and warning installations of the H-TRONplus

The sound of an acoustic beep and a message on the display informs you about the status and/or malfunctions of the H-TRONplus and/or the system.



Warning: In case the beeps can not be heard, e.g. in a noisy room, check the display regularly. This way you can detect malfunctions in a timely manner.

	Beep, display	Description
Alarms ERROR – Messages	Continuous beeping, ERROR 01 – 11	11 alarms, ERROR 01 to 11, indicate an imminent or an actual malfunction or the completion of a function.
STOP- Warning	1 beep / minute, STOP	The pump is in STOP mode and is not delivering insulin . This can be caused by user putting pump into STOP mode directly or as a result of a pump ERROR code.

2.2 Handling and display

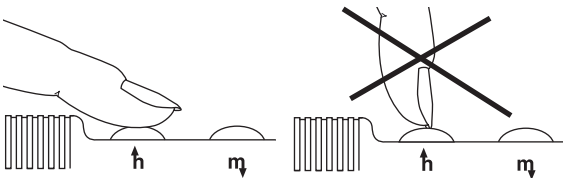
Programming of the pump involves the use of three buttons: the **S**-, **h**- and **m**-button.

All inputs are shown on the display and are followed by one or several short (●) and/or long (■) beeps.

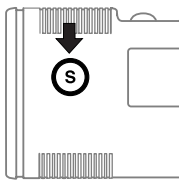
Audible beeps		
Graphic description of the signal	Duration and timing of each signal	Signal description
●	Short beep	Button pressed
■	Long beep every minute	Pump in STOP
■ ● ● ●	Long beep, three short beeps	Change to RUN
● ● ● ■	Three short beeps, long beep	Change to STOP. No insulin administration.
■ ■ ■	Continuous beeping	ERROR. Read and understand section 7 "Alarms."

Activating the display

In order to save power, the display (LCD - Liquid Crystal Display) goes blank after 30 seconds if no buttons are pressed. It remains blank until buttons are pressed. To view the display again, press the **h**- and **m**- buttons at the same time for one second. Any other button can also be pressed, but then not only is the display illuminated, but the function related to this button will also be displayed.

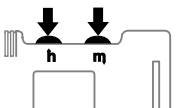


Caution: Never press any button with a sharp item or your fingernails. Use the pad of your finger instead to prevent puncturing the buttons.



S-button

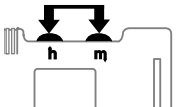
The **S**-button, the select button, is for choosing the functions of the pump. A cursor, represented as a small triangle ◀(or)▶, moves with each press of the **S**-button and indicates the currently selected function.



h-button/m-button

Pressing one of these rubber-type buttons will activate the selected function. To set a value press the

- **h**-button, to increase the value (↑), or
- **m**-button, to decrease the value (↓).



Some of the functions are activated by simultaneous pressing of the **h**- and **m**-buttons. Other functions start automatically after a defined period and a confirmation by a beep.

Scrolling function

(Available for the functions "program the basal rate" and "set the clock").

In order to enter a particular value, a button must normally be pressed several times. However, in certain situations if you hold down a pressed button, the value will automatically change. You can hold the button ("scroll") until the desired value appears on the display. The value can of course still be corrected with the buttons. If you use the scrolling function, check to make sure the entered values are correct. No audible beeps are given by the pump while scrolling.



Checking programmed values

Always check the display to make sure that you have programmed the desired values.

2.3 Operating status (STOP/RUN)

The "operating status" of the H-TRONplus may be either STOP or RUN. In RUN the word RUN appears in the display and the pump delivers insulin. In STOP the word STOP appears in the display and the pump does not deliver insulin.

Operations can only be performed if the H-TRONplus is in the correct operating status.

The H-TRONplus has the following basic and special functions. You will find detailed instructions for these functions on the pages indicated below:

Basic functions	Operating Status	Page
Set the clock	STOP	27
Program and review the basal rates	STOP	28
Reset for a new cartridge	STOP	41
Prime the infusion set	STOP	42
Change the pump status/start and stop pump delivery	STOP/RUN	45
Program a bolus	RUN	46
Special functions		
Recall data memory	RUN	49
Set temporary basal rates	STOP	52
Control the beeps	STOP	55
Control the STOP-Alarm	STOP	56
Basal rate lock/unlock	STOP	57

2.4 Programmable settings



Warning: Incorrect programming of the pump will lead to an incorrect dose of insulin. Do not operate the H-TRONplus Insulin Pump without knowing your personal settings. The pump must be programmed with your personal settings prior to starting the therapy! Make sure that if you are not experienced, your doctor or health care professional checks your personal settings.



Caution: Prior to using a replacement, a spare or a new pump, always check the settings in order to avoid an incorrect dosage.

Your H-TRONplus is supplied by Disetronic with a standard program. You may need to change these standard programmed values to meet your needs after discussion with your doctor or health care team.

The following settings can be changed by Disetronic if requested by your doctor:

Setting	Standard	Ranges
basal rate step	0.1 U.	0.1 – 10 U.
maximum hourly basal rate	10 U.	1 – 40 U.
bolus step per push of a button	0.5 U.	0.1 – 1.9 U.
maximum single bolus	25 U.	0.1 – 95 U.
Option: Bolus limit within a specified time frame		
Time frame	OFF	1 – 24 hours
Bolus limit	OFF	0 – 99.9 U.
Bolus limit reached (ERROR 05)	OFF	0 – 99.9 U.
Temporary basal rate increase	12 h	1 – 24 h
Temporary basal rate decrease	4 h	1 – 24 h
Automatic off (ERROR 06)	OFF	0 – 24 h
Cartridge low warning (ERROR 10)	20 U.	10 – 50 U.

If the parameters set in your pump do not meet your needs, changes can be made by Disetronic. Consult your doctor or health care team about your personal programming. If in doubt, please contact Disetronic to discuss how to proceed.

2.5 Accessories and disposables



Caution: Use only specified accessories and disposables, because only these items are tested for correct delivery of insulin when used with the pump. The reuse of any materials designed for single use may increase the risk of an infection, of a malfunction and of a wrong dosage. Use the cartridge and the infusion set only once! Regularly replace these items according to the instructions provided with the accessories.



Caution: Most of the accessories and disposable materials are specially designed for the use with the H-TRONplus pump. Always have **extra** accessories, disposable materials and **extra** batteries available in order to prevent involuntary interruption of pump therapy.



Motor (2)

Batteries (Special PowerPacks)

The H-TRONplus requires two 3-volt silver oxide batteries to power the electronics and the motor.

The compartments for the batteries are marked as follows:

- compartment for the motor battery: 2 (for ERROR 02)
- compartment for the electronic battery: 3 (for ERROR 03) (farthest from the cartridge chamber)



Electronic (3)

Always have **extra** batteries available and pay attention to the following:

- Do not store the batteries in the refrigerator or freezer. High humidity affects battery life.
- Prevent early discharge of the batteries by preventing contact between the batteries themselves and between the batteries and any other metal (coins, keys, etc.). Always keep batteries in the original package until ready to use.
- For operating the pump, the temperature of the batteries must be +41°F to +122°F (+5°C to +50°C).

- To tighten batteries use only the Disetronic **battery tool** until the top of the battery is level with the pump case. Over tightening may cause pump case damage.
- Use only Disetronic batteries. Otherwise, the settings and alarms may be incorrect and/or the pump could be damaged.

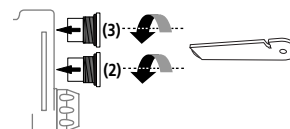
The working life of the batteries (2 and 3) is affected by usage of the pump, rates, temperature, etc. Batteries should last at least 4 weeks.



Caution: For preventing water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.

Battery tool



Use only the battery tool to insert, tighten or remove the batteries. Use the hole in the top to put the tool on your key chain.



Piston rod

The piston rod moves the plunger of the cartridge forward. Due to wear it has to be replaced every year. Always make sure that the cog wheel spins freely on the piston rod. The nylon end cap should spin and the metal rod should be clean.



Cartridge

The sterile-packed cartridge set contains all items required to fill the cartridge with insulin. The cartridge is a **sterile product intended for single use only**. Sterility is guaranteed for unopened packaging up to the indicated expiration date. Do not use if package is damaged. **Do not reuse single use materials.** Reuse of single use materials might lead to a malfunction of the pump and to the administration of an incorrect amount of insulin and/or an infection.



Pump Adapter

The pump adapter makes a reliable connection between the pump, cartridge, and the infusion set. At the same time, it seals the cartridge compartment with "O"-rings. Inspect the "O"-rings before putting the pump adapter on the pump. They should not show signs of wear. The two small openings on the adapter allow air pressure to equalize. The holes should not be plugged or the air pressure can not equalize. The pump adapter has to be changed every 6 months.

Infusion set

The infusion set connects the pump, the cartridge and the body, and is therefore a crucial part of insulin pump therapy. The insulin is delivered from the cartridge in the pump through the infusion set into the subcutaneous tissue. The cannula is usually placed in the abdomen or the hip. All infusion sets are sterile and intended for single use only. Disetronic offers a wide range of infusion sets. The infusion set is a sterile-packed product intended for single use only.

Do not use if package is damaged. Do not reuse single use materials. All Disetronic infusion sets are PVC free. They are made of polyethylene only or polyethylene covered with polyurethane, thus they are well tolerated by the skin and neutral to insulin. The diameter of the infusion set tubing has been reduced in order to achieve faster and more economical priming.

Common length of the tubing	filling volume U-100
60 cm / 24"	10 Units
80 cm / 31"	13 Units
110 cm / 43"	18 Units

Protective coverings, carrying systems and other accessories

Specially designed carrying systems allow you to carry the H-TRONplus on or underneath your clothes. Please consult the special catalogue "Insulin Pump Supplies and Accessories" for more information or contact Disetronic.

This section includes:

3.1 Insert and change batteries

3.1.1 Insert the batteries

3.1.2 Change the batteries

3.2 Insert/remove both batteries

3.2.1 Insert both batteries

3.2.2 Remove both batteries

3.3 Set the clock

3.4 Program the basal rates

3.4.1 Program a basal rate for each hour

3.4.2 Program the same basal rate for several hours

3.4.3 Change basal rates

3.5 Review basal rate programming



Caution: The pump and disposable materials should be used for the first time in the presence of your doctor or health care team. Regular medical examinations are required.

If the pump user is not able to independently operate the H-TRONplus pump, e.g. due to a disability or other special conditions, make sure that the assisting person strictly follows the instructions contained in this manual.



Caution: Always pay attention to the **operating status of the H-TRONplus (STOP or RUN)**. Operations can only be performed if the H-TRONplus is in the correct operating status. In this reference manual, you will find the necessary operating status indicated on the headline in bold type. Always make sure that you are in the required operating status and change the status if required according to the instructions in the chapter 5.1 "start and stop pump delivery."

Remember these symbols for functions and operations

Symbol	Description
--------	-------------

◀ (or) ▶	A small triangle, or cursor, indicates the selected function.
----------	---

→	This arrow indicates when you have to do something, e.g. to press a button.
---	---

<div> <div>prime</div> <div>reset</div> <div>clock</div> <div>basal</div> </div> <div> <div>◀</div> <div>88:88</div> <div>▶</div> </div> <div> <div>data</div> <div>units</div> <div>bolus</div> <div>temp</div> </div>	<div> <div>STOP</div> <div>RUN</div> </div> <div> <div>ERROR</div> </div>	<div> <div>88:88</div> </div> <div> <div>8.8.8.8</div> </div>	A schematic representation of the display illustrates the corresponding information before and/or after an operation.
---	---	---	---

<div>●</div> <div>■</div>	This symbol represents the audible beeps. All inputs are shown on the display and are followed by one or several short (●) and/or long (■) beeps.
---------------------------	---

3.1 Insert and change batteries



Caution: In order to prevent water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.



Caution: Removing both batteries simultaneously will cause the data memory to be erased (including current settings, such as, temporary basal rate changes or programmed bolus), the loss of the remaining cartridge volume, the history of alarms, ERROR 10 and ERROR 01, and the time setting. Only the basal rate programming is not lost. Reinsert the batteries according to section 3.1.1 "insert the batteries" after having removed them simultaneously. You need to reprogram/verify all pump settings and start with a new cartridge. If not, your insulin remaining counter will not match the actual contents of your cartridge. If the cartridge in the pump actually has less than 315.0 units, the "cartridge low warning" alarm (ERROR 10) will not alert you when the cartridge is low on insulin. When the cartridge is empty, the pump will alarm ERROR 04 (occlusion).

The compartments for the batteries are marked as follows:


- compartment for the motor battery: 2 (for ERROR 02).
- compartment for the electronic battery: 3 (for ERROR 03) (farthest from the cartridge chamber).

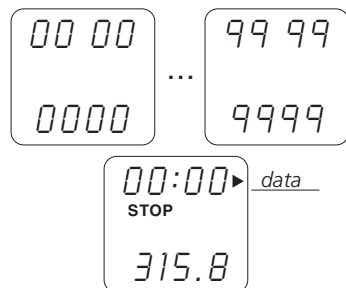
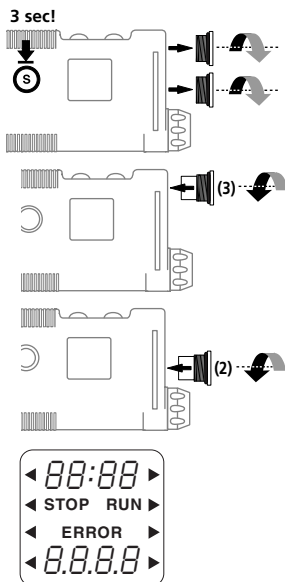
Always have **extra** batteries available and pay attention to the following:

- Do not store the batteries in the refrigerator or freezer. High humidity affects battery life.
- Prevent early discharge of the batteries by preventing contact between the batteries themselves and between the batteries and any other metal (coins, keys, etc.). Always keep batteries in the original package until ready to use.
- For operating the pump, the temperature of the batteries must be +41°F to +122°F (+5°C to +50°C).
- To tighten batteries use only the Disetronic **battery tool** until the top of the battery is level with the pump case. Over tightening may cause pump case damage.
- Use only Disetronic batteries. Otherwise, the settings and alarms may be incorrect and/or the pump could be damaged.
- Take the used batteries to a battery recycling location or if no such location exists, return the batteries to Disetronic. Please do not dispose of them in the household trash.

3.1.1 Insert the batteries

No battery is in the pump

- ➔ Remove the protective covers from the battery compartments using the battery tool. Store the covers.
- ➔ Press the **S**-button for at least 3 seconds. The pump will discharge any static load to prevent electronics problems.
- ➔ Take one battery out of the packaging and check to see if the "O"-ring is present and correctly placed.
- ➔ **Always place a new battery into compartment 3 (electronic) first.** Always turn the battery until it is tight. Tight means the top of the battery is level with the pump case. **DO NOT OVER TIGHTEN, AND USE THE BATTERY TOOL () ONLY!** The display illuminates and shows four lines of numbers and words, and eight cursors.
- ➔ Take a second battery out of the packaging and check to see if the "O"-ring is present and correctly placed.
- ➔ Screw this second battery into compartment 2 (motor). Always turn the battery until it is tight. Tight means the top of the battery is level with the pump case. **DO NOT OVER TIGHTEN.**
- ➔ Press any button to start the "pump self-check." During this countdown on the display, all electrical systems are checked.



● A short beep sounds when the "pump self-check" starts.

The numbers from 0 to 9 scroll on the display.

■ A long beep sounds at the end of the "pump self-check." The pump is automatically set to STOP. If the pump displays ERROR 07, remove both batteries. Reinsert the batteries by following the procedure described above.

Energy Saver:

Note: The display goes blank after 30 seconds if no buttons are pressed. It remains blank until buttons are pressed. To view the display again, press **h** and **m** at the same time for one second.

3.1.2 Change the batteries

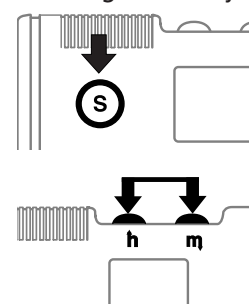
status **STOP**



Caution: Change the battery only in a dry environment and do not remove both batteries simultaneously. Check that the black "O"-ring is correctly installed and seated properly. See section 3.1 "insert and change batteries" for further precautions.

It is usually not necessary to change both batteries at the same time. When the pump alarms ERROR 02, change the battery in compartment 2 (motor). When the pump alarms ERROR 03, change the battery in compartment 3 (electronic).

To change a battery:



- ➔ Press **S** and hold for three seconds to silence the ERROR alarm if present.
- ➔ Press **h** and **m** and hold for a least three seconds to change to STOP, unless the pump is already in STOP.
- ➔ Remove the battery from the pump using the battery tool, and replace it with a new battery.
- Be sure the battery is tight. Tight means the top of the battery is level with the pump case. **DO NOT OVER TIGHTEN.** Over tightening may cause pump case damage.
- ➔ Check the clock, and review basal rate programming. (See section 3.5).
- ➔ Change to RUN

3.2 Insert/remove both batteries

3.2.1 Insert both batteries

Inserting the batteries will power the pump and start the time to technical inspection counter. This counter is set for 24 months. Please refer to the section 10.1 "repair and technical inspection" in this reference manual for further information.

Once the pump is powered, you need to program the pump to your individual needs.

3.2.2 Remove both batteries

status **STOP** or **RUN**

! **Caution:** Only remove both batteries if required to clear some pump alarms or if you are stopping use of the pump for a longer time period (e.g. when changing to a replacement pump, troubleshooting some pump alarms or when returning the pump for technical inspection). Insulin delivery, as well as the time to technical inspection counter, will be interrupted if both batteries are removed.

- 1. → Change the operating status to **STOP**, if the pump is still in **RUN**.
- 2. → Remove **both batteries** using the battery tool and cover the openings of the compartments with the battery compartment protective covers.

If both batteries are removed, three events occur when the batteries are reinserted:

- Data Memory is cleared (including current settings such as temporary basal rate changes or programmed bolus and the history of bolus and ERRORS). Only the basal rate programming is not lost. Note that if only one battery is removed and reinserted or replaced, data memory is not reset.
- The pump is reset to a “full” cartridge volume and displays 315.0 units. If the cartridge in the pump actually has less than 315.0 units, the “cartridge low warning” alarm (ERROR 10) will not alert you when the cartridge is low on insulin. When the cartridge is empty, the pump will alarm ERROR 04 (occlusion).
- The clock is reset to 00:00 hours. The clock must be reprogrammed to the correct time before restarting the pump. **Failure to reset the clock may result in incorrect basal insulin delivery.**

3.3 Set the clock

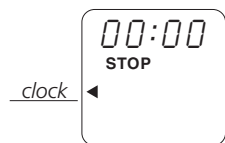
status **STOP**

The H-TRONplus uses a 24-hour (military time) clock. To help in using a 24-hour clock, the table below shows the conversion from a 12-hour clock to a 24-hour clock.

12-hour clock vs. 24-hour clock			
12-hour clock	24-hour clock	12-hour clock	24-hour clock
1:00 AM	01:00	1:00 PM	13:00
2:00 AM	02:00	2:00 PM	14:00
3:00 AM	03:00	3:00 PM	15:00
4:00 AM	04:00	4:00 PM	16:00
5:00 AM	05:00	5:00 PM	17:00
6:00 AM	06:00	6:00 PM	18:00
7:00 AM	07:00	7:00 PM	19:00
8:00 AM	08:00	8:00 PM	20:00
9:00 AM	09:00	9:00 PM	21:00
10:00 AM	10:00	10:00 PM	22:00
11:00 AM	11:00	11:00 PM	23:00
12:00 PM	12:00	12:00 AM	24:00

Example: If the time is now 1:39 PM, the 24-hour time is 13:39
Example: If the time is now 6:15 PM, the 24-hour time is 18:15
Example: If the time is now 8:30 AM, the 24-hour time is 08:30

To set the clock, the Disetronic H-TRONplus must be in **STOP**. If during programming, no button is pressed for eight seconds, the pump returns automatically to the default **STOP** display.



1. → Press the **S**-button 3 times or until the cursor points to "clock."

Setting the hours

2. → Within 8 seconds, press **h** to set the hours. The **h** symbol represents hours.

Setting the minutes

3. → Within eight seconds after the last press of the **h**-button, press **m** to set the minutes. The **m** symbol represents minutes.

Optional scrolling: If **h** or **m** is held down, the display advances five numbers and then scrolls numbers quickly. Hold **h** or **m** until the desired hour or minute is reached.



Eight seconds after the clock is set, the time is automatically entered into memory by the pump. The cursor returns to "data," the pump emits a long beep (■■■■) and displays the time.

Note: If you do not wait for the long beep (■■■■) after setting the clock, and try to put the pump in RUN, you will inadvertently turn off the beeps.

Instructions on how to "control the beeps" are in section 6.3. Instructions on how to "control the STOP-Alarm" are in section 6.4.

3.4 Program the basal rates

status **STOP**



Warning: Incorrect programming of the pump will lead to an incorrect dose of insulin. Do not operate the H-TRONplus Insulin Pump without knowing your personal settings. The pump must be programmed with your personal settings prior to starting the therapy! Make sure that if you are not experienced, your doctor or health care professional checks your personal settings.

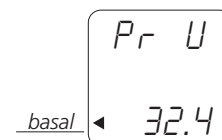
The H-TRONplus delivers insulin every three minutes, 24-hours a day. This flow of insulin, measured in units per hour, is called the "basal rate" and is calculated to meet your basic insulin needs. The H-TRONplus "basal rate profile" consists of 24 hourly basal rates.

Your individual basal rates must be programmed into the pump before you start your therapy. The basal rate for each hour of the day is programmed on a separate display screen.

Note: The insulin amounts and other programming numbers used in this reference manual are only examples; your programming may differ.

3.4.1 Program a basal rate for each hour

To program basal rates for each hour individually, the H-TRONplus must be in STOP. If during programming, no button is pressed for twelve seconds, the cursor returns to "basal." Twelve seconds later the pump returns to the default STOP display.



1. → Press **S** until the cursor points to "basal." The display shows:

- "Pr U" (basal rate programming is unlocked and allows basal rate changes). "Pr L" will be displayed if the basal rate programming is locked. Refer to section 6.5 "basal rate lock/unlock" for more information. "Pr U" must be displayed in order to change the basal rate programming.
- "Basal rate total" (amount of insulin delivered by the basal rates over 24 hours).

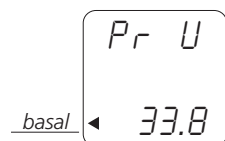


2. → Within 12 seconds, press **S** again to select the first hour.

The display shows the first hour as 00:01, which means midnight to 1:00 AM. It also displays the basal rate for this hour.



3. → Within 12 seconds, press the **h**-button to increase the basal rate. Press the **m**-button to decrease the basal rate. Optional scrolling: If **h** or **m** is held down, the display increases or decreases five numbers and then scrolls through the numbers quickly. Hold **h** or **m** until the desired basal rate is reached.
4. → Within 12 seconds, press **S** to select the next hour. The display will advance one hour and shows:



- 01:02, which means 1:00 AM to 2:00 AM
 - The basal rate for this hour.
- Press **h** or **m** to increase or decrease the basal rate.
5. → Program the remaining hours by pressing **S** to advance the hours, and **h** or **m** to increase or decrease the basal rate. Remember to program all 24 hours.
 6. Twelve seconds after the last button is pressed, the pump returns to the "basal rate total." Check the "basal rate total" to ensure it is correct. Do this by adding up the rates for all 24 hours. This amount should equal the amount shown on the display.
 7. Twelve seconds after the "basal rate total" is displayed, the pump returns to the default STOP display showing insulin remaining.

Use this table to convert the "pump basal rate" display time to AM/PM time when you are programming your basal rates. Example:

- If the pump basal rate display is 03:04, the AM/PM time is 3 AM to 4 AM
- If the pump basal rate display is 16:17, the AM/PM time is 4 PM to 5 PM

Pump basal rate display	AM/PM time	Pump basal rate display	AM/PM time	Pump basal rate display	AM/PM time
00:01	12–1 AM	08:09	8–9 AM	16:17	4–5 PM
01:02	1–2 AM	09:10	9–10 AM	17:18	5–6 PM
02:03	2–3 AM	10:11	10–11 AM	18:19	6–7 PM
03:04	3–4 AM	11:12	11 AM–12 PM	19:20	7–8 PM
04:05	4–5 AM	12:13	12–1 PM	20:21	8–9 PM
05:06	5–6 AM	13:14	1–2 PM	21:22	9–10 PM
06:07	6–7 AM	14:15	2–3 PM	22:23	10–11 PM
07:08	7–8 AM	15:16	3–4 PM	23:24	11 PM–12 AM

3.4.2 Program the same basal rate for several hours

A basal rate can be copied for one or more hours. If during programming, no button is pressed for 12 seconds, the cursor returns to "basal." Twelve seconds after the "basal rate total" is displayed, the pump returns to the default STOP display.

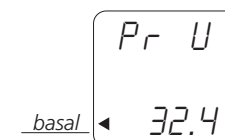
To copy the basal rate:

1. Refer to section 3.4.1 "program a basal rate for each hour" step 1 and 2 and
→ press **S** to select the hour to be copied.
 2. → Within 12 seconds, press and release **h** and **m** at the same time:
 - the basal rate is "copied" to the next hour.
 - continue to press **h** and **m** to copy the basal rate for as many hours as needed.
 3. Twelve seconds after the last button is pressed, the pump returns to the "basal rate total."
- Check the "basal rate total" to ensure it is correct.

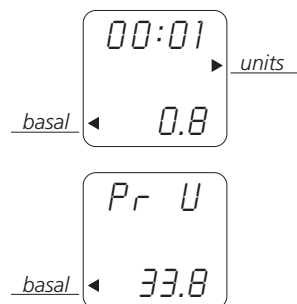
Twelve seconds after the "basal rate total" is displayed, the pump returns to the default STOP display.

3.4.3 Change basal rates

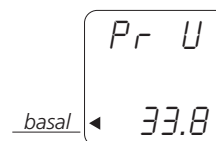
Any hourly basal rate can be changed without affecting the other basal rates. To change basal rates, the H-TRONplus must be in STOP. If during programming, no button is pressed for 12 seconds, the cursor returns to "basal." Twelve seconds later the pump returns to the default STOP display.



1. → Press **S** until the cursor points to "basal." The display shows:
 - "Pr U" (basal rate programming is unlocked and allows basal rate changes). "Pr L" will be displayed if the basal rate programming is locked. Refer to section 6.5 "basal rate lock/unlock" for more information. "Pr U" must be displayed in order to change the basal rate programming.



- “Basal rate total” (amount of insulin delivered by the basal rates over 24 hours).
- 2. → Within 12 seconds, press and HOLD **S**: The display scrolls through the hours, without changing the basal rates. Release **S** when the hour to be changed is reached. Within 12 seconds, change the basal rate using **h** or **m**.
- 3. Twelve seconds after the last button is pressed, the pump returns to the “basal rate total.” Check the “basal rate total” to ensure it is correct.
- 4. Twelve seconds after the “basal rate total” is displayed, the pump returns to the default STOP display.



- 3. If a change is necessary at a certain hour, increase or decrease with **h** or **m**.
- 4. Twelve seconds after the last button is pressed, the pump returns to the “basal rate total.” Check the “basal rate total” to ensure it is correct.
- 5. Twelve seconds after the “basal rate total” is displayed, the pump returns to the default STOP display.

3.5. Review basal rate programming

status **STOP**

The basal rates should be reviewed:

- After any programming change
- When the batteries are changed
- After clearing an alarm ERROR 07

To review the basal rate programming, the H-TRONplus must be in STOP.



- 1. → Press **S** until the cursor points to “basal.” The display shows:
 - “Pr U” (basal rate programming is unlocked and allows basal rate changes). “Pr L” will be displayed if the basal rate programming is locked. Refer to section 6.5 “basal rate lock/unlock” for more information.
 - “Basal rate total” (amount of insulin delivered by the basal rates over 24 hours).
- 2. Within 12 seconds:
 - press and release **S** repeatedly to review the basal rates, or,
 - press and HOLD **S** and the display will scroll through the basal rates at one-second intervals.

This section includes:

4.1 Fill the cartridge

- 4.1.1 Prepare the cartridge (Steps 1 to 7)
- 4.1.2 Fill the cartridge (Steps 8 to 17)
- 4.1.3 Insert the piston rod into the cartridge (Steps 18 to 22)
- 4.1.4 Attach the infusion set and insert the cartridge into the cartridge compartment (Steps 23 to 30)

4.2 Half-fill the plastic cartridge

4.3 Fill the cartridge using the EasyFill

- 4.3.1 Prepare the cartridge (Steps 1 to 7)
- 4.3.2 Fill the cartridge using the EasyFill (Steps 8 to 15)
- 4.3.3 Remove the cartridge from the EasyFill (Steps 16 to 21)

4.4 Reset new cartridge

- 4.4.1 Reset new full cartridge
- 4.4.2 Reset new half-full plastic cartridge

4.5 Prime the infusion set

4.6 Select and prepare an infusion site



Warning: Use only fast acting U-100 insulin prescribed by your doctor or health care professional.

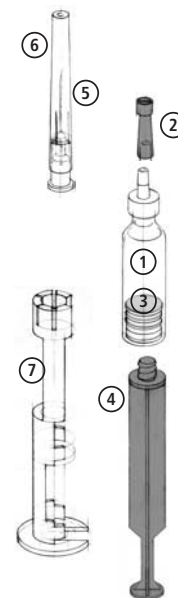


Caution: Use only the specified cartridges. The cartridges are **sterile products intended for single use only**. Sterility is guaranteed for unopened packaging up to the indicated expiration date. Do not use if package is damaged. **Do not reuse single use materials.** Reuse of single use materials might lead to a malfunction and to the administration of an incorrect amount of insulin. Always work with clean hands.

4.1 Fill the cartridge



Warning: Air bubbles in the cartridge cause the infusion of air instead of insulin. Your body will not receive the required amount of insulin. An "occlusion" ERROR 04 may be delayed. Remove these bubbles according to the instructions while filling the cartridge. Cold insulin may release dissolved air when warmed. Use only insulin at room, or preferably body, temperature when filling the cartridge.

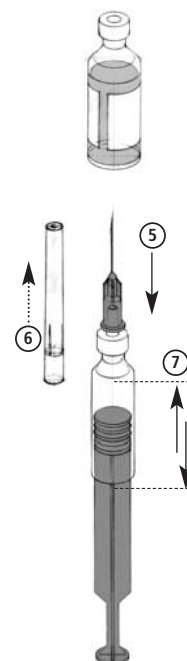


A cartridge set consists of:

1. Cartridge 3.15 ml (plastic or glass)
2. Cartridge protective cap
3. Cartridge plunger
4. Plunger rod
5. Filling needle with protective cover
6. Protective cover
7. Filling aid "EasyFill" (optional)

The H-TRONplus Insulin Pump functions with 3.15ml plastic or glass cartridges. The following example shows how to fill a cartridge. Always consult the instructions for use included with your cartridge sets.

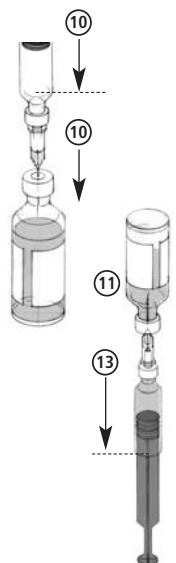
4.1.1 Prepare the cartridge (Steps 1 to 7)



1. → Get everything ready:
 - New cartridge and plunger rod
 - New cartridge protective cap
 - New filling needle, with protective cover
 - Insulin at room temperature to minimize formation of air bubbles.
2. → Wash your hands
3. → Remove the cartridge with plunger rod and protective cap from blister pack.
4. → Remove filling needle with protective cover from blister pack. Be careful not to touch the open end of the filling needle or cartridge tip, as they are sterile.
5. → Place filling needle with cover on cartridge tip and tighten. Tighten it by "pressing and turning" at the same time.
6. → Remove protective needle cover. Ensure that nothing touches the needle.
7. → Move the plunger back and forth in the cartridge two times to distribute the lubricant.
Pull the plunger back to the 3.15 mark of the plastic cartridge, or the bottom edge of the glass cartridge, to fill the cartridge with air.

4.1.2 Fill the cartridge (Steps 8 to 17)

Move the plunger rod slowly and steadily when filling the cartridge. Do not move the plunger rod side-to-side when filling the cartridge; the seal between the plunger and the inside of the cartridge may break.



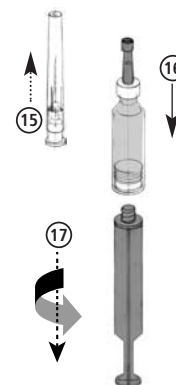
8. → Set the bottle of insulin on a hard surface, like a table.
9. → Wipe bottle top with an alcohol wipe.
10. → Push the tip of the filling needle down into the insulin bottle. Push the plunger rod down so that all air from the cartridge enters the insulin bottle. Make sure that the tip of the needle does not contact the insulin while air is pushed into the insulin bottle.
11. → While holding steady pressure against the plunger rod with your thumb, invert the bottle so that the filling needle and cartridge are pointing upwards into the insulin bottle. Remove your thumb from the plunger rod. Insulin will begin to fill the cartridge. Do not pull on the plunger rod while it is moving. Make sure that the tip of the filling needle stays in the insulin during the entire filling procedure.
12. → Slowly pull the plunger rod in a straight line and completely fill the cartridge. Be careful not to move the plunger rod side-to-side.



Caution: Remove any air bubbles by tapping on the cartridge to dislodge them. Push them back into the insulin bottle with the plunger rod.



13. → The cartridge is full when the top of the plunger of the plastic cartridge is even with the 3.15 marker line, or when the bottom edge of the plunger of the glass cartridge is even with the bottom edge of the glass cartridge.
14. → Remove the filling needle and the cartridge from the insulin bottle. Put the protective needle cover on the filling needle.



15. → Remove the filling needle and protective cover from the cartridge.
16. → Push the cartridge protective cap TIGHTLY onto the cartridge until it is snug.
17. → Remove the plunger rod by turning it counterclockwise out of the plunger. Take care not to move the plunger during removal.

The cartridge is now ready for the insertion of the piston rod.

4.1.3 Insert the piston rod into the cartridge (Steps 18 to 22)

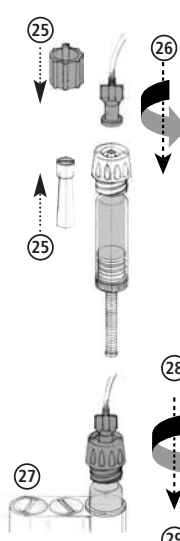


18. → Ensure that the cartridge protective cap is on the cartridge and TIGHTLY in place.
19. → Spin the nylon end cap. If the nylon end cap does not spin freely, replace the piston rod.
20. → Spin the cog wheel to a position that is more than half way down from the end cap. If the cog wheel does not spin freely, clean or replace the piston rod.
21. → Insert the nylon end cap into the cartridge plunger. Push the nylon end cap until it is snugly in place. DO NOT TRY TO TWIST OR TIGHTEN.
22. → Spin the cog wheel until it reaches the bottom of the cartridge. Turn the cog wheel back away from the bottom of the cartridge 1/4 turn to loosen it slightly.

The cartridge and piston rod are now ready for the infusion set to be attached.

4.1.4 Attach the infusion set and insert the cartridge into the cartridge compartment (Steps 23 to 30)

23. → Get everything ready:
 - filled cartridge, with plastic protective cap and threaded piston rod
 - pump adapter with intact "O"-ring
 - infusion set

- 
24. → Snap the pump adapter onto the cartridge, over the protective cap.
 25. → Remove the:
 - protective cap from the cartridge
 - protective cap from the luer-lock of the infusion set. Do not touch the areas previously covered by the protective caps as these are sterile areas.
 26. → Screw the luer-lock of the infusion set clockwise into the threads of the pump adapter.
 27. → Set the pump on its end, or hold it vertically.
 28. → Insert the cartridge, with the piston rod and pump adapter with infusion set attached, into the cartridge compartment. If necessary, rotate the cartridge slowly until it and the piston rod drop into the cartridge compartment.
 29. → Screw the pump adapter clockwise into the cartridge compartment.
 30. → Be sure that the pump adapter is tight. Be sure the infusion set luer-lock connection is tight, but do not over-tighten. Over tightening may crack the luer lock.

4.2 Half-fill the plastic cartridge

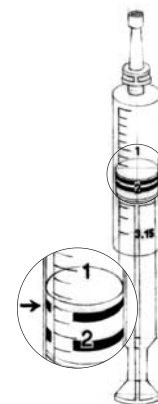
Special conditions may require that you half-fill the plastic cartridge.

Note: Do not half-fill glass cartridges. Plastic cartridges have a scale which allow you to half-fill these cartridges. Plastic cartridges are half-filled when the top of the plunger is half-way between the 1.4 ml and 1.6 ml marker lines.



Caution: In order to use half-filled plastic cartridges you need to follow a specific procedure to re-set a new half-filled cartridge. Please refer to section 4.4.2 of this reference manual.

To half-fill a plastic cartridge follow steps one to 30 in section 4.1 "fill the cartridge." However, make sure that you follow steps 6 and 13 as slightly modified below:



Step 6:

- Move the plunger back and forth in the cartridge two times to distribute the lubricant. Pull the plunger back so that the top of the plunger is between the 1.4 and 1.6 ml marker lines.

Step 13:

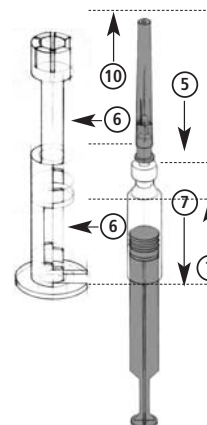
- The cartridge is half-full when the top of the plunger is half-way between the 1.4 ml and 1.6 ml marker lines.

4.3 Fill the cartridge using the EasyFill

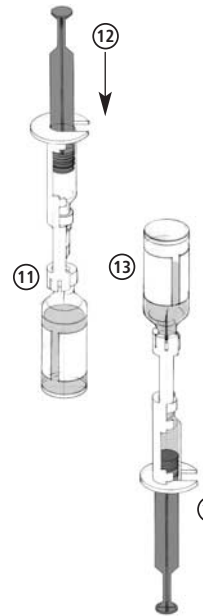
The EasyFill is an optional tool designed to facilitate the filling of glass or plastic cartridges.

4.3.1 Prepare the cartridge (Steps 1 to 7)

1. → Get everything ready:
 - EasyFill
 - New cartridge and plunger rod
 - New cartridge protective cap
 - New filling needle, with protective cover
 - Insulin at room temperature to minimize formation of air bubbles.
2. → Wash your hands.
3. → Remove the cartridge with plunger rod and protective cap from blister pack.
4. → Remove filling needle with protective cover, from blister pack. Be careful not to touch the open end of the filling needle or cartridge tip, as they are sterile.
5. → Place filling needle with cover on cartridge tip and tighten. Tighten it by pressing and turning at the same time.
6. → Insert the cartridge with the filling needle into the EasyFill. The bottom edge of the cartridge should be level with the "clamping disk" of the EasyFill. Press the cartridge firmly into place until it snaps.
7. → Move the plunger back and forth in the cartridge two times to distribute the lubricant. Pull the plunger back to fill the cartridge with air.



4.3.2 Fill the cartridge using the EasyFill (Steps 8 to 15)



8. → Set the bottle of insulin on a hard surface, like a table.
9. → Wipe the bottle top with an alcohol wipe.
10. → Remove protective needle cover. Ensure that nothing touches the needle.
11. → Push the "bottle holder" of the EasyFill onto the top of the insulin bottle. Note that the filling needle has punctured the rubber membrane of the insulin bottle.
12. → Push the plunger rod down so that all air from the cartridge enters the insulin bottle.
13. → While holding steady pressure against the plunger rod with your thumb, invert the bottle so that the filling needle and cartridge are pointing upwards into the insulin bottle. Remove your thumb from the plunger rod. Insulin will begin to fill the cartridge. Do not pull on the plunger rod while it is moving, to avoid unnecessary formation of air bubbles.
14. → Slowly pull the plunger rod in a straight line and completely fill the cartridge.

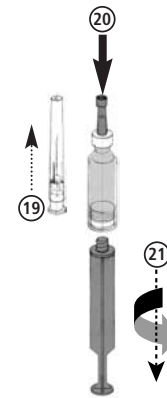


Caution: Remove any air bubbles by tapping on the cartridge to dislodge them. Push them back into the insulin bottle with the plunger rod.

15. The cartridge is full when there are no air bubbles and the plunger is at the bottom of the cartridge. When using the EasyFill, the plunger cannot be pulled out of the cartridge.

4.3.3 Remove the cartridge from the EasyFill (Steps 16 to 21)

16. → Remove the insulin bottle from the EasyFill "bottle holder."
17. → Put the protective needle cover on the filling needle.
18. → Remove the cartridge and the filling needle with the protective needle cover from the EasyFill.
19. → Remove the filling needle and protective cover from the cartridge by turning and pulling it.
20. → Push the cartridge protective cap TIGHTLY onto the cartridge until it is snug.



21. → Remove the plunger rod by turning it counterclockwise out of the plunger. Take care not to move the plunger during removal.

The cartridge is now ready for the insertion of the piston rod. To insert the piston rod into the cartridge go to section 4.1.3.

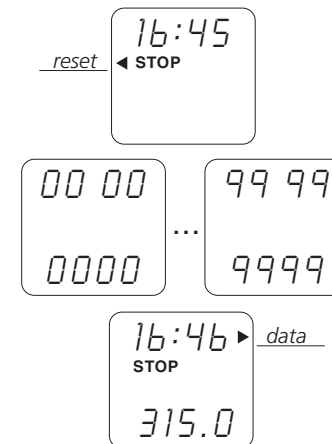
4.4 Reset new cartridge

status **STOP**



Warning: With every cartridge change, you must reset the pump either to 315.0 or 150.0 U to correspond to the cartridge contents. Otherwise, the counter for the actual cartridge volume will be inaccurate. This will lead to inappropriate alarms. The alarm "ERROR 04" will occur instead of the alarms "ERROR 10" or "ERROR 01," when the cartridge is empty.

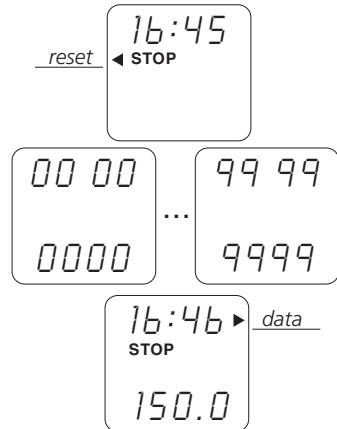
4.4.1 Reset new full cartridge



1. → Press **S** until the cursor points to "reset."
2. → Within eight seconds, **press h and m at the same time** (⏸) and release. The display scrolls from 0 to 9 (Pump self-check). When the scrolling is complete, a long beep sounds, 315.0 appears, and the cursor points to "data."

If during programming, no button is pressed for eight seconds, the pump returns to the default STOP display.

4.4.2 Reset new half-full plastic cartridge



- Press **S** until the cursor points to "reset."
- Within eight seconds, **press and hold either h or m** (↔) until the pump beeps twice.
- Then **immediately press h and m at the same time** (↔) and release.
 - The display scrolls from 0 to 9 (Pump self-check).
 - When the scrolling is complete, a long beep sounds 150.0 appears, and the cursor points to "data."

4.5 Prime the infusion set

status **STOP**



Warning: Never carry out the function "priming the infusion set" with an **infusion set inserted** in an infusion site. Otherwise you risk an uncontrolled delivery of insulin into your body. With disconnectable infusion sets, be sure you have disconnected prior to programming, changing, or priming.



Warning: Air bubbles in the infusion set cause the infusion of air instead of insulin. Your body will not receive the required amount of insulin. An "occlusion" ERROR 04 may be delayed. Remove these bubbles according to the instructions, while priming the infusion set.

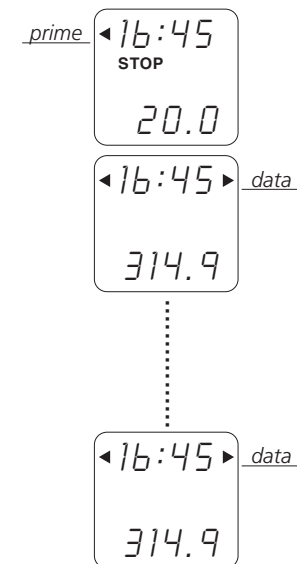


Caution: Only use **infusion sets** which are designed expressly for use with Disetronic pumps. Other infusion sets may not have been checked for compatibility with Disetronic pumps and may, therefore, endanger your health if used. Always have extra infusion sets with you. This will allow you to exchange components when needed.

The infusion sets are **sterile products intended for single use only**. Sterility is guaranteed for unopened packaging up to the indicated expiration date. Do not use if package is damaged. **Do not reuse single use materials**. Reuse of single use materials might lead to an infection and/or to a malfunction of the pump and to the administration of an incorrect amount of insulin.

Prime the infusion set:

The H-TRONplus will prime 20 units of insulin at a time. If insulin is not dripping from the infusion set needle at the end of the prime, repeat the prime. When insulin drips from the end of the needle, press any button to stop the prime. An infusion set is filled when air is eliminated from the set and insulin drips from the end of the needle. If during programming no button is pressed for eight seconds, the pump returns to the default STOP display.



- Press **S** until the cursor points to "prime."
- Within eight seconds, press **h** and **m** and **S** at the same time, and release. The pump begins priming.
- Hold the pump vertically while priming to help send any air to the top of the cartridge for elimination during priming.
 - The prime can be stopped at any time, by pressing ANY button.
 - The insulin remaining on the lower line of the display decreases as the priming continues. The pump displays two cursors, one at "prime," and one at "data," because the "insulin remaining" is decreasing.
 - when the prime is complete, the pump beeps and returns to the default STOP display. The cursor points to "data."
 - Inspect your infusion set for any excessive air bubbles.

4.6 Select and prepare an infusion site

status **STOP**



Caution: Never insert an infusion set into an infusion site without having removed all air from the infusion set.



Caution: Always follow the instructions given by your doctor or health care team. Follow the instructions given in the instructions for use of the infusion set you are using.



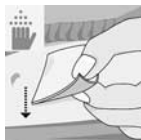


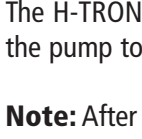
Caution: When blood is detected in the infusion set, you have most likely nicked a blood vessel causing the risk of an occlusion of the infusion set. Select a new infusion site and replace the infusion set.

Site selection

Your health care team will help you select your infusion site areas, according to a planned site rotation pattern.

Site preparation

Proper site preparation is essential to reduce the risks of infection. Your health care team will give you site preparation guidelines, such as:

- ①  1. Wash your hands thoroughly.
- ②  2. Scrub the infusion site with an antiseptic.
- ③  3. Insert the infusion set needle, according to the instructions for your infusion set. Use transparent site dressing and safety loop, if necessary.
- ④  4. Inspect the site at least once or twice each day for irritation or infection.
 - if you see redness or swelling, change the infusion set immediately.
 - if there is infection, change immediately, and contact your health care team. Signs of infection may include, but are not limited to, pain, a lump, redness, heat, or drainage.
 - you should change infusion sites regularly, according to the infusion set package insert.

The H-TRONplus is now ready for operation, this means you may change the status of the pump to RUN.

Note: After inserting a new soft cannula-type infusion set, you must bolus to fill the air space in the cannula to get insulin to the tip (according to the infusion set package insert). Failure to do this step could result in missed insulin, possibly leading to hyperglycemia.

This section includes:

- 5.1 Start and stop pump delivery**
- 5.2 Program a bolus**
- 5.3 Cancel a bolus**
- 5.4 Change a cartridge and an infusion set**
- 5.5 Change an infusion set only**

Once the H-TRONplus is set-up you can start operating the device.



Warning: Only change the pump to RUN if the pump is fully and correctly equipped (including filled cartridge, adapter, primed infusion set) and programmed with your personal settings.

The "operating status" of the H-TRONplus may be either STOP or RUN. In RUN the word RUN appears in the display and the pump delivers insulin. In STOP, the word STOP appears in the display and the pump does NOT deliver insulin.

The operations can only be performed if the H-TRONplus is in the correct operating status.

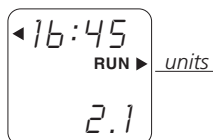
5.1 Start and stop pump delivery status **RUN/STOP**

When the H-TRONplus Insulin Pump is in STOP, it does not deliver insulin, but it may be programmed. When the pump is in RUN, insulin is delivered at the preprogrammed basal rate and boluses may be programmed, if required.

To determine whether the pump is in STOP or RUN, press both **h** and **m** at the same time for one second. The pump displays the actual status, either STOP or RUN.

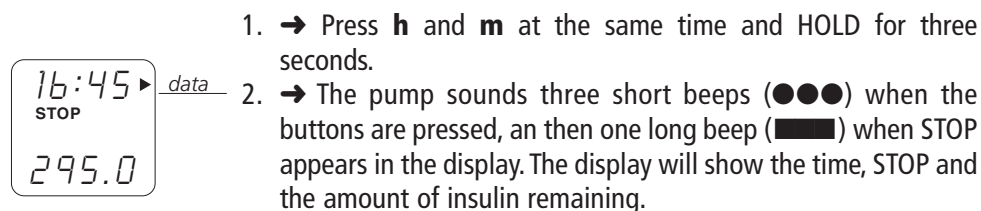
To change from STOP to RUN status **STOP**

1. → Press **h** and **m** at the same time and HOLD for three seconds.
2. The pump sounds one long beep (■) when the buttons are pressed, and then three short beeps (●●●) when RUN appears.
3. Once the pump is in RUN, the display will show the programmed actual time, the current hourly basal rate and the status RUN.



To change from RUN to STOP

status **RUN**

- 
1. → Press **h** and **m** at the same time and HOLD for three seconds.
 2. → The pump sounds three short beeps (●●●) when the buttons are pressed, and then one long beep (■) when STOP appears in the display. The display will show the time, STOP and the amount of insulin remaining.

STOP-Alarm

When the pump is in STOP, it beeps once every minute to remind you that it is stopped and that no insulin is being delivered. This beeping is the STOP-Alarm. The stop alarm is activated when the pump is first changed to RUN and then returned to STOP. It can be silenced (see section 6.4 "control the STOP-Alarm"). To re-activate the STOP-Alarm, put the pump in RUN and then into STOP.

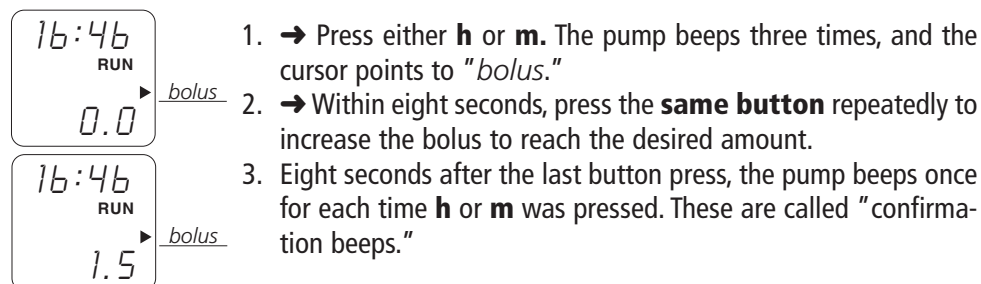
5.2 Program a bolus

status **RUN**

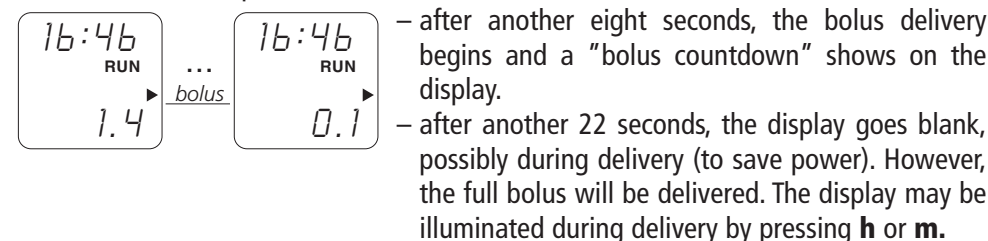
The amount of a bolus is determined by your health care team's guidelines, based on your blood glucose value, your food intake, and your activity level. To program a bolus, the H-TRONplus must be in RUN. If during programming, before entering a bolus amount, no button is pressed for eight seconds, the pump returns to the default RUN display.



Caution: Determine with your doctor or health care team the quantity of insulin you need to administer. Be certain you know your personal carbohydrate/insulin ratio and your blood glucose correction ratio.

- 
1. → Press either **h** or **m**. The pump beeps three times, and the cursor points to "bolus."
 2. → Within eight seconds, press the **same button** repeatedly to increase the bolus to reach the desired amount.
 3. Eight seconds after the last button press, the pump beeps once for each time **h** or **m** was pressed. These are called "confirmation beeps."

Note: the confirmation beeps will not sound if the beeps are silenced. See section 6.3 "control the beeps."

- 
- after another eight seconds, the bolus delivery begins and a "bolus countdown" shows on the display.
 - after another 22 seconds, the display goes blank, possibly during delivery (to save power). However, the full bolus will be delivered. The display may be illuminated during delivery by pressing **h** or **m**.

5.3 Cancel a bolus

status **RUN**

1. Before the confirmation beeps, the bolus amount can be reset to 0.0 by pressing the opposite button (Opposite button **h** or **m** from the button used to set the bolus).
2. After the confirmation beeps, the bolus can be canceled by changing the pump to STOP (press and hold **h** and **m** at the same time until the display shows STOP).
3. During delivery, a bolus can be interrupted by **changing the pump to STOP** (press and hold **h** and **m** at the same time until the display shows STOP).



Caution: The pump will not deliver any insulin while it is in STOP.

The amount and time of the last ten boluses can be reviewed with the "recall data memory" feature, see section 6.1.3 "recall recent boluses."

5.4 Change a cartridge and an infusion set status **STOP**



Warning: Never change the cartridge or carry out the function "priming the infusion set" with an **infusion set inserted** in an infusion site. Otherwise you risk an uncontrolled delivery of insulin into your body. With disconnectable infusion sets, be sure you have disconnected prior to programming, changing, or priming.



Warning: Air bubbles in the cartridge and in the infusion set cause the infusion of air instead of insulin. Your body will not receive the required amount of insulin. An "occlusion" ERROR 04 may be delayed. Remove these bubbles according the instructions in section 4.1 "fill the cartridge" and section 4.5 "prime the infusion set."

To change a cartridge and infusion set, the pump must be in STOP.

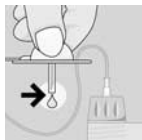
1. Wash hands.
2. Remove the infusion set from the body first, then from the pump and discard it safely in the proper container.
3. Remove the cartridge from the pump and discard it in the proper container. Save the piston rod for continued use.
4. Fill the new cartridge with insulin and attach the new infusion set as described in section 4 "prepare the cartridge and attach the infusion set."

Note: Some infusion sets require an extra bolus after initial insertion to take up the air space. Refer to the insertion instructions of your infusion set.

5.5 Change an infusion set only

status **STOP**

Change the infusion set according to the instructions for use of the infusion set you are using.



1. Remove the infusion set from the body first, then from the pump and discard it safely in the proper container.
2. Attach a new infusion set to the pump.
3. Hold the pump vertically and prime the infusion set. Repeat the prime sequence if necessary, until insulin drips from the end of the needle. Stop the prime by pressing any button when insulin begins to drip.
4. Insert the infusion set as described in section 4.1.4 "attach the infusion set..."

This section includes:

6.1 Recall data memory

- 6.1.1 Recall insulin remaining
- 6.1.2 Recall total amount of insulin since midnight
- 6.1.3 Recall recent boluses
- 6.1.4 Recall alarm messages

6.2 Set temporary basal rate

- 6.2.1 Set temporary basal rate increase
- 6.2.2 Set temporary basal rate decrease

6.3 Control the beeps

6.4 Control the STOP-Alarm

6.5 Basal rate lock/unlock



Warning: Incorrect programming of the pump will lead to an incorrect dose of insulin. Do not operate the H-TRONplus Insulin Pump without knowing your personal settings. The pump must be programmed with your personal settings prior to starting the therapy! Make sure that if you are not experienced, your doctor or health care professional checks your personal settings.

6.1 Recall data memory

status **RUN**



Caution: If both batteries are removed at the same time, some data memory information (insulin remaining, total amount of insulin delivered since midnight, boluses delivered, ERROR messages) in the pump is lost. If only one battery is removed and replaced, data memory is not lost.

The H-TRONplus memory stores the following information:

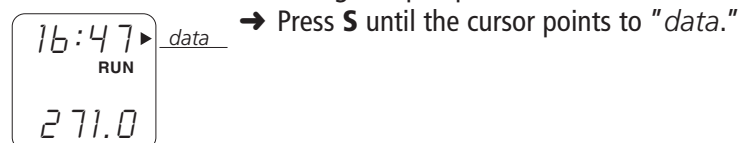
- Insulin remaining in the cartridge.
- Total amount of insulin delivered since midnight.
- Recent boluses delivered, including the time and amount of the last 10 boluses.
- ERROR Messages, including the time and code of the last five alarms.

To access data, the pump must be in RUN.

- By pressing **S** repeatedly, the pump displays the entire sequence of data information.
- If **S** is not pressed within twelve seconds, the pump returns to the default display.

6.1.1 Recall insulin remaining

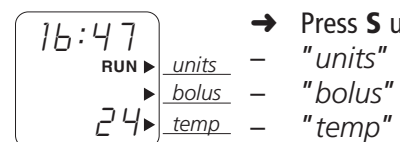
To recall the insulin remaining, the pump must be in RUN.



Caution: The indication of the cartridge volume on the display is a calculated value. When a new cartridge (full or half-filled) is inserted the pump must be reset for a full or half-filled cartridge, otherwise the displayed value of the remaining amount of insulin is incorrect.

6.1.2 Recall total amount of insulin since midnight

To recall the total amount of insulin infused since midnight, the pump must be in RUN.

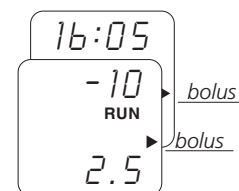
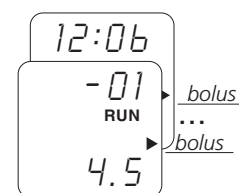


The total amount of insulin is displayed next to "temp," this total is rounded to the nearest whole unit.

6.1.3 Recall recent boluses

The H-TRONplus memory stores information on the last 10 boluses. If the pump has not delivered 10 boluses since both batteries were inserted at the same time, the pump will only display the boluses that have been delivered.

To recall bolus information, the pump must be in RUN.

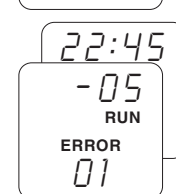
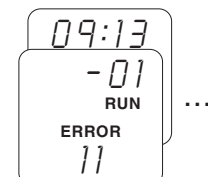


- Press **S** until the cursor points to "bolus."
 - The display alternately flashes "-01" and the "time of the last bolus" on the top line (-01 means the last bolus).
 - The bolus amount is on the bottom line.
 If **S** is not pressed again within 12 seconds, the pump returns to the default RUN display.
- Within 12 seconds, press **S** again and the second most recent bolus is displayed.
 - The cursor still points to "bolus."
 - The top line of the pump display alternately flashes "-02" and the "time of the second most recent bolus" (-02 means the second most recent bolus).
 - The bolus amount is on the bottom line.
- Press **S** repeatedly to recall remaining boluses. Bolus amounts and times are recalled in sequence (-03, -04, etc.). If **S** is not pressed within 12 seconds, the pump returns to the default RUN display.

6.1.4 Recall alarm messages

The H-TRONplus memory stores information on the last five alarms. If the pump has not had five alarms since both batteries were inserted at the same time, the pump will only display the alarms that have occurred.

To recall alarm messages, the pump must be in RUN.



- Press **S** until the word ERROR appears in the display. Notice that there are no cursors.
 - The display alternately flashes "-01" and the "time of the last alarm" on the top line (-01 means the last alarm).
 - The ERROR code is on the bottom line.
 If **S** is not pressed again within 12 seconds, the pump returns to the default RUN display.
- Within 12 seconds, press **S** again and the second most recent alarm message is displayed.

- The top line of the pump display alternately flashes “-02” and the “time of the second most recent alarm” (-02 means the second most recent alarm).
- The ERROR code is on the bottom line.

If **S** is not pressed within 12 seconds, the pump returns to the default RUN display.

3. → Press **S** repeatedly to recall remaining alarms. ERROR codes and times are recalled in sequence (-03, -04, etc.).

If **S** is not pressed within 12 seconds, the pump returns to the default RUN display.

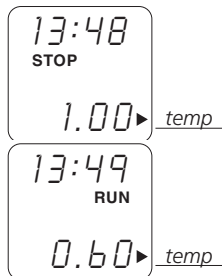
If planning to remove both batteries, record any data memory information that will be needed later, as inserting both batteries will lead to a reset of the data memory.

6.2 Set temporary basal rate

status **STOP**

6.2.1 Set temporary basal rate increase

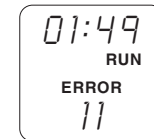
To set a temporary basal rate increase, the pump must be in STOP. If during programming, no button is pressed for eight seconds, the pump returns to the default STOP display.



1. → Press **h** until the cursor points to “temp.” The display shows 1.00 to indicate that it is programmed for 100% of the original basal rate.
2. → Within eight seconds, repeatedly press **h** to increase the basal rate by 10% increments to the desired level.
 - Eight seconds after the last button is pressed, the pump beeps TWICE for each time **h** was pressed. These are “confirmation beeps.” If the beeps have been turned off, the pump will NOT give confirmation beeps.
 - Immediately after the confirmation beeps, the pump changes to RUN. The display shows the temporary basal rate increase percentage on the bottom line. For example, 1.10 means 110% of the original basal rate will be delivered (a 10% increase).

Notes:

- A temporary basal rate increase lasts 12 hours (standard setting, see section 2.4 “programmable settings”), unless programmed otherwise. The pump beeps three times on the hour, each hour, as a reminder.
- If the beeps have been turned off, the pump will NOT beep three times on the hour as a reminder.
- The basal rate can be increased up to 200% (twice the original basal rate). The display shows 2.00 to indicate that it is programmed for 200% of the original basal rate.
- An incorrect entry can be corrected, before the confirmation beeps, by pressing **m**. The basal level is returned to 1.00 (100% of original basal rate).
- The temporary increase can be canceled by changing from RUN to STOP. The alarm ERROR 11 confirms the cancellation. Silence the alarm by pressing and holding **S** for three seconds. Then, either re-program a new temporary basal rate increase, or change from STOP to RUN.
- The delivery of a bolus does not interrupt the temporary basal rate increase.
- After the 12-hour temporary basal rate increase (standard setting), the pump automatically returns to the original basal rate. The pump alarms ERROR 11 and beeps continuously to confirm the end of the temporary basal rate increase. The pump remains in RUN. Silence the alarm by pressing **S** for three seconds. Press **S** again to clear the alarm message from the display.



6.2.2 Set temporary basal rate decrease



Warning: If a basal rate decrease is programmed to a value of 0%, no insulin will be delivered for four hours (standard setting).

To set a temporary basal rate decrease, the pump must be in STOP. If during programming, no button is pressed for eight seconds, the pump returns to the default STOP display.



1. → Press **m** until the cursor points to "temp." The display shows 1.00 to indicate that it is programmed for 100% of the original basal rate.

2. → Within eight seconds, repeatedly press **m** to decrease the basal rate by 10% increments to the desired level.

– Eight seconds after the last button is pressed, the pump beeps ONCE for each time **m** was pressed. These are "confirmation beeps". If the beeps have been turned off, the pump will NOT give confirmation beeps.

– Immediately after the confirmation beeps, the pump changes to RUN. The display shows the temporary basal rate decrease percentage on the bottom line. For example, 0.90 means 90% of the original basal rate will be delivered (a 10% reduction).



Notes:

- A temporary basal rate decrease lasts 4 hours (standard setting, see section 2.4 "programmable settings"), unless programmed otherwise. The pump beeps three times on the hour, each hour, as a reminder.
- If the beeps have been turned off, the pump will NOT beep three times on the hour as a reminder.
- If the beeps have been turned off, the pump will NOT give confirmation beeps.
- The basal rate can be decreased to 0%. The display shows 0.00 to indicate that it is programmed for 0% of the original basal rate. **No insulin will be delivered for 4 hours**, or as otherwise programmed!
- An incorrect entry can be corrected, before the confirmation beeps, by pressing **h** once. The basal level is returned to 1.00 (100% of original basal rate).
- The temporary decrease can be canceled by changing from RUN to STOP. The alarm ERROR 11 confirms the cancellation. Silence the alarm by pressing and holding **S** for three seconds. Then, either re-program a new temporary basal rate decrease, or change from STOP to RUN.
- The delivery of a bolus does not interrupt the temporary basal rate decrease.



- After the 4-hour temporary basal rate decrease, the pump automatically returns to the original basal rate. The pump alarms ERROR 11 and beeps continuously to confirm the end of the temporary basal rate decrease. The pump remains in RUN. Silence the alarm by pressing **S** for three seconds. Press **S** again to clear the alarm message from the display.

6.3 Control the beeps

status **STOP**

The H-TRONplus Insulin Pump beeps when a button is pressed, when there is an alarm or when there is a warning. The beep "tones" alert you to a change in the pump. The beeps may be long (■) or short (●).



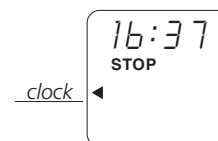
Warning: If you silence beeps, check the display of the H-TRONplus Insulin Pump regularly. This is the only way you will be aware of any changes in the pump in a timely manner.

The following beeps can be silenced:

- Warning beeps
- Confirmation beeps
- Beeps when buttons are pressed

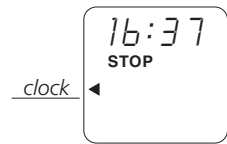
Alarms cannot be silenced. **To silence the beeps**, the pump must be in STOP.

If during programming, no button is pressed for eight seconds, the pump returns to the default STOP display.



1. → Press **S** until the cursor points to "clock."
2. → Within eight seconds, press **h** and **m** at the same time (the pump will confirm this action by a short (●) beep) and hold for three seconds. The beeps are silenced when the cursor points to "data."

To restore the beeps, the pump must be in STOP.



1. → Press **S** until the cursor points to "clock."
2. → Within eight seconds, press **h** and **m** at the same time and hold for three seconds. The beeps are restored when the cursor points to "data," and the pump beeps.

Note: If both batteries are removed at the same time, the beeps are automatically restored when batteries are reinserted.

6.4 Control the STOP-Alarm

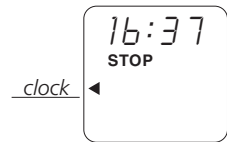
status **STOP**



Warning: When the H-TRONplus Insulin Pump is in the STOP display, there is no insulin being delivered. To inform you that no insulin is being administered, the pump gives a long beep (STOP-Alarm) every minute. When the pump beeps, the display shows STOP and illuminates for 30 seconds. Controlling the STOP-Alarm will suppress this warning function. Do not silence the STOP-Alarm, unless the pump is not used for several hours.

To silence the STOP-Alarm, the pump must be in STOP.

If during programming, no button is pressed for eight seconds, the pump returns to the default STOP display.



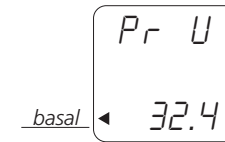
1. → Press **S** until the cursor points to "clock."
2. → Within eight seconds, press **h** and **m** at the same time briefly. The pump beeps when the buttons are pressed.
3. → Immediately, again press **h** and **m** at the same time, briefly. The STOP alarm has been silenced when the cursor points to "data." All other beeps and alarms are still active.

When the pump is changed to RUN, the STOP-Alarm is restored. When the pump is changed to STOP again, the STOP-Alarm will sound.

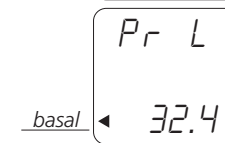
6.5 Basal rate lock/unlock

status **STOP**

The basal rate program can be "locked" or "unlocked". When it is locked, the basal rates cannot be changed. When it is unlocked, the basal rates can be changed. To lock the basal rates, the pump must be in STOP. If during programming, no button is pressed for 12 seconds, the pump returns to the default STOP display.



1. → Press **S** until the cursor points to "basal." The display shows "Pr U" because the program is unlocked.

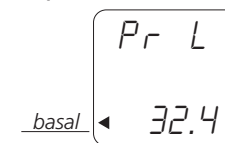


2. → Within 12 seconds, press **h**, **m**, and **S** at the same time until "Pr L" is displayed. The basal rate program is now locked.

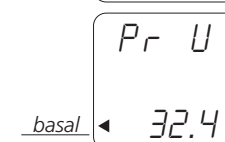


After 12 seconds, the pump returns to the default STOP display.

To unlock the basal rates, the pump must be in STOP. If during programming, no button is pressed for 12 seconds, the pump returns to the default STOP display.



1. → Press **S** until the cursor points to "basal." The display shows "Pr L" because the program is locked.



2. → Within 12 seconds, press **h**, **m**, and **S** at the same time until "Pr U" is displayed. The basal rate program is now unlocked.



After 12 seconds, the pump returns to the default STOP display.

ERROR CODES

ID 420.0545/V03/03.01

01 Empty Cartridge	07 System Alarm
02 Low Motor Battery (2)	8x Technical Inspection Alert
03 Low Electronic Battery (3)	09 Technical Inspection Due
04 Occlusion	10 Cartridge Low Warning
05 Bolus Limit Reached	11 End of Temporary Basal Rate
06 Automatic Off	

 **DISETRONIC** 1-800-688-4578

Read instruction manual before using.

Rx only

Short explanation of the error code list shown on the back of the H-TRONplus Insulin Pump.

Always refer to the detailed instructions concerning "Alarms (ERROR)" in section 7.

No.	Meaning of the ERROR	What you have to do	Page
01	Empty Cartridge	Silence alarm. Insert new cartridge. Change infusion set.	60
02	Low Motor Battery (2)	Silence alarm. Replace motor battery.	60
03	Low Electronic Battery (3)	Silence alarm. Replace electronic battery.	61
04	Occlusion	Silence alarm. Check blood glucose value. Change infusion set, or check piston rod, or check pump.	62
05	Bolus Limit Reached	Silence alarm. See manual.	65
06	Automatic Off	Silence alarm. See manual.	66
07	System Alarm	Remove batteries. Press S for three seconds. Reinsert batteries, set clock, check basal rates.	67
8X	Technical Inspection Alert	Silence alarm. Schedule technical inspection.	68
09	Technical Inspection Due	Silence alarm. Schedule technical inspection. Begin alternate insulin delivery method.	69
10	Cartridge Low Warning	Silence alarm. Insert new cartridge soon.	70
11	End of Temporary Basal Rate	Silence alarm.	71

This section includes:

- 7.1 Alarm ERROR 01: Empty Cartridge**
- 7.2 Alarm ERROR 02: Low Motor Battery (2)**
- 7.3 Alarm ERROR 03: Low Electronic Battery (3)**
- 7.4 Alarm ERROR 04: Occlusion**
- 7.5 Alarm ERROR 05: Bolus Limit Reached**
- 7.6 Alarm ERROR 06: Automatic Off**
- 7.7 Alarm ERROR 07: System Alarm**
- 7.8 Alarm ERROR 8x: Technical Inspection Alert**
- 7.9 Alarm ERROR 09: Technical Inspection Due**
- 7.10 Alarm ERROR 10: Cartridge Low Warning**
- 7.11 Alarm ERROR 11: End of Temporary Basal Rate**



Warning: The H-TRONplus contains a safety system that constantly analyzes the pump. The H-TRONplus ERROR messages indicate an important change of the operating status or irregularities in insulin administration. The pump will be set to STOP immediately when the ERROR message appears or shortly after (Except ERROR 11). Insulin administration will be stopped. In order to maintain insulin administration, you need to act immediately according to the instructions given for each ERROR code.

The H-TRONplus Insulin Pump has an internal-analysis and alarm system to protect you. The dual microprocessors detect certain conditions that are not harmful, but require immediate action. If the pump alarms with an error code, the pump:

Displays ERROR and a two-digit ERROR code, and beeps continuously.

The beeping can be silenced by pressing **S** and holding for three seconds. The alarm message will clear from the display when the ERROR is corrected, or when **S** is pressed again.

7.1 Alarm ERROR 01: Empty Cartridge



If the calculated (according to the insulin remaining counter) insulin remaining in the cartridges reaches 0.0, the pump alarms and displays ERROR 01. The word STOP appears and the pump beeps continuously. The cartridge must be changed now.

Do the following:

- Silence alarm by holding **S** for three seconds.
- Change the cartridge and the infusion set.
- Reset for new cartridge.
- Prime the infusion set and
- change the pump to RUN.

7.2 Alarm ERROR 02: Low Motor Battery (2)

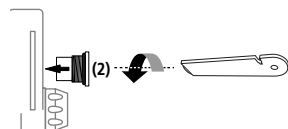


When the voltage of the battery in compartment 2 reaches a low level, the alarm ERROR 02 appears in the display and the pump beeps continuously.

The pump checks the voltage of the motor battery every hour, every time the pump delivers insulin, and every time the pump is switched from STOP to RUN.


Do the following:

- Silence alarm by holding **S** for three seconds.
- Check the display. If it shows:
 - STOP, try to change to RUN. If no alarm sounds, and the display shows RUN, do not change the battery.
 - STOP, and will NOT change to RUN and alarms again (ERROR 02), change the battery. Change the pump to RUN.
 - RUN, press **S** to clear the display. Do not change the battery unless the alarm ERROR 02 will not clear.
- Be sure that the battery is correctly inserted, and has an intact "O"-ring according to section 3.1 "insert and change batteries."



Note:

- The pump may operate for a period of time even when the voltage is low. The pump will continue to deliver insulin and may alarm every hour until the battery voltage drops to a level which triggers continuous beeping and the alarm ERROR 02 will not clear. When the alarm ERROR 02 will not clear and the pump will not change to RUN, change the battery immediately.
- **Do not remove both batteries at the same time after a battery alarm, in order to keep the data memory.** Change only the battery in compartment 2 when the pump alarms ERROR 02.
- Always keep extra batteries immediately available. Keep batteries in their original package.

**Caution:** For preventing water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.

7.3 Alarm ERROR 03: Low Electronic Battery (3)

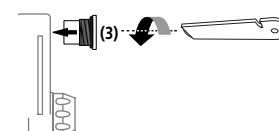


When the voltage of the battery in compartment 3 reaches a low level, the alarm ERROR 03 appears in the display and the pump beeps continuously.

The pump checks the voltage of the electronic battery every hour, every time the pump delivers insulin, and every time the pump is switched from STOP to RUN.

Do the following:

- Silence alarm by holding **S** for three seconds.
- Check the display. If it shows:
 - STOP, try to change to RUN. If no alarm sounds, and the display shows RUN, do not change the battery.
 - STOP, and will NOT change to RUN and alarms again (ERROR 03), change the battery. Change the pump to RUN.



→ RUN, press **S** to clear the display. Do not change the battery unless the alarm ERROR 03 will not clear.

- Be sure that the battery is tight, and correctly inserted, and has an intact "O"-ring according to section 3.1 "insert and change batteries".

Note:

- The pump may operate for a period of time even when the voltage is low. The pump will continue to deliver insulin and may alarm every hour until the battery voltage drops to a level which triggers continuous beeping and the alarm ERROR 03 will not clear. When the alarm ERROR 03 will not clear and the pump will not change to RUN, change the battery immediately.
- **Do not remove both batteries at the same time after a battery alarm in order to keep the data memory.** Change only the battery in compartment 3 when the pump alarms ERROR 03.
- Always keep extra batteries immediately available. Keep batteries in their original package.



Caution: For preventing water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.

7.4 Alarm ERROR 04: Occlusion (please see scheme on page 98)

An ERROR 04 may be caused by:



- An empty cartridge
- A reused cartridge
- A blocked infusion set
- A dirty or damaged piston rod
- A low battery in compartment 2 (motor)

When one of these conditions occurs, the pump motor stops. When the motor stops, the pump alarms ERROR 04, changes to STOP and beeps continuously.

If an alarm ERROR 04 appears, check your blood glucose value, because delivery of insulin may have been interrupted for several hours. If blood glucose is high, treat according to your health care team's instructions.

With a disconnect infusion set do the following:

1. → Press **S** and hold for three seconds to silence the alarm, ERROR 04 stays on the display.
2. → Check blood glucose. If elevated, treat according to your health care team's instructions. Go to step 3.
3. → Disconnect the infusion set from the site. Prime.
 - If the pump does not alarm ERROR 04 again, insert a new infusion set into the skin according to the instructions for use of the infusion set. Reconnect infusion set to the site after making sure that insulin is dripping from the connector needle, and there is no air in the system. Change pump to RUN.
 - If the pump does alarm ERROR 04, go to step 4.
4. → Check to make sure that the infusion set is still disconnected from the site. Remove the cartridge from the pump with piston rod, adapter, and infusion set attached. Prime.
 - If the pump does not alarm ERROR 04, go to step 5.
 - If the pump alarms ERROR 04, change battery in compartment 2 (motor) as described in section 3.1.2 and prime.
 - If the pump does not alarm ERROR 04, insert the cartridge with piston rod, adapter, and infusion set back into the pump. Screw the adapter onto the cartridge chamber. Prime until insulin drips from the end of the connector needle and there is no air in the system. Reconnect the infusion set to the infusion site. Put pump into RUN.
 - If the pump alarms ERROR 04, go to step 7.
5. → Insert cartridge with piston rod, adapter, and infusion set re-attached to the pump. Screw the adapter onto the cartridge chamber. Remove infusion set from the adapter. Prime.
 - If the pump does not alarm ERROR 04, attach a new infusion set, prime, and reconnect after ensuring that insulin drips from the end of the connector needle and there is no air in the system. Change the pump to RUN.
 - If the pump alarms ERROR 04, go to step 6.

6. ➔ Remove cartridge with piston rod, and replace with new cartridge and new piston rod, if available. Insert new cartridge with piston rod, reset the pump for a new cartridge, attach a new infusion set, and prime.
 - If the pump does not alarm ERROR 04, change the pump to RUN. Reconnect the infusion set to the site after making sure that insulin is dripping from the connector needle and there is no air in the system.
 - If the pump alarms ERROR 04, go to step 7.
7. ➔ Change to your back-up insulin delivery device or contact your health care team for an alternate insulin therapy plan. Call Disetronic at 1 (800) 688 4578.

With a non-disconnect infusion set do the following:

1. ➔ Press **S** and hold for three seconds to silence the alarm, ERROR 04 stays on the display.
2. ➔ Check blood glucose value. If elevated, treat according to your health care team's instructions. Go to step 3.
3. ➔ Remove the infusion set from the site. Prime.
 - If the pump does not alarm ERROR 04, and insulin drips from the needle at the end of the infusion set, remove the infusion set from the adapter. Screw new infusion set onto adapter. Prime. Insert the infusion set into a newly prepared infusion site making sure that insulin is dripping from the needle, and there is no air in the system. Change pump to RUN.
 - If the pump alarms ERROR 04, go to step 4.
4. ➔ Check to make sure that the infusion set is removed from the site. Remove the cartridge from the pump with piston rod, adapter, and infusion set attached. Prime.
 - If the pump does not alarm ERROR 04, go to step 5.
 - If the pump alarms ERROR 04, change battery in compartment 2 (motor) and prime.
 - If the pump does not alarm ERROR 04, insert the cartridge with piston rod, adapter, and infusion set back into the pump. Replace infusion set with a new one and prime. Insert the infusion set into a newly prepared infusion site. Put pump into RUN.
 - If the pump alarms ERROR 04, go to step 7.

5. ➔ Insert cartridge with piston rod, adapter, and infusion set re-attached to the cartridge chamber of the pump. Screw the adapter onto the cartridge chamber. Remove infusion set from the adapter. Prime.
 - If the pump does not alarm ERROR 04, attach a new infusion set and prime. Insert a new infusion set into a newly prepared infusion site after ensuring that insulin drips from the needle and there is no air in the system. Change the pump to RUN.
 - If the pump alarms ERROR 04, go to step 6.
6. ➔ Remove cartridge with piston rod, and replace with new cartridge and new piston rod, if available. Insert new cartridge with piston rod, reset the pump for a new cartridge, attach a new infusion set, and prime.
 - If the pump does not alarm ERROR 04, change the pump to RUN. Insert the infusion set to a newly prepared infusion site after making sure that insulin is dripping from the needle and there is no air in the system.
 - If the pump alarms ERROR 04, go to step 7.
7. ➔ Change to your back-up insulin delivery device or contact your health care team for an alternate insulin therapy plan. Call Disetronic at 1 (800) 688 4578.

Note: The piston rod needs to be replaced every 12 months. The adapter needs to be replaced every 6 months. A damaged or worn out piston rod or adapter could lead to an ERROR 04.

7.5 Alarm ERROR 05: Bolus Limit Reached



A safety limit on the amount of bolus insulin that can be delivered in a period of time may be set with special programming. This alarm is not activated by Disetronic, unless ordered by your health care team.

When programmed, the display shows ERROR 05 if the bolus limit is reached. The pump remains in RUN and beeps continuously. The alarm does not affect the basal insulin delivery.

Do the following:

- Silence alarm by holding **S** for three seconds. ERROR 05 stays on the display.
- Press **S** to clear the display.
- Contact your health care team about the need to possibly re-evaluate the bolus limit.

The range of the preset bolus limit can be modified by Disetronic upon written confirmation by your doctor or health care provider. For the possible ranges see section 2.4 "programmable settings."

7.6 Alarm ERROR 06: Automatic Off



This safety feature alarms if a button has not been pressed within a set amount of time. It can remind you to check the pump regularly. This alarm is not activated by Disetronic, unless ordered by your health care team.

When this safety feature is activated, and if no button (**h**, **m**, or **S**) is pressed within the programmed time limit (1-24 hours), the pump will display an alarm ERROR 06, change to STOP, and beep continuously.

Do the following:

- Silence alarm by holding **S** for three seconds. ERROR 06 stays on the display.
- Change the pump to RUN.
- Contact your health care team about the need to possibly re-evaluate the automatic off limit, if necessary.

The "automatic OFF" can be modified by Disetronic upon written confirmation by your doctor or health care provider. For the possible ranges see section 2.4 "programmable settings".

7.7 Alarm ERROR 07: System Alarm



The alarm ERROR 07 cannot be silenced by pushing a button. Remove BOTH batteries, at the same time, to silence alarm ERROR 07.



Caution: If both batteries are removed and then reinserted or replaced:

- Data Memory is cleared.
- The pump is reset to a "full" cartridge volume and displays 315.0 units
- The clock is reset to 00:00 hours.

For more information see section 3.2.2 "remove both batteries".



Caution: For preventing water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.

Do the following:

1. → Disconnect or remove the infusion set. Remove both batteries. Press **S** and hold for three seconds.
2. → Reinsert the battery in compartment 3 (electronic). Be sure that it is tight. Tight means that the top of the battery is level with the pump case. Do not over tighten.
3. → Press **S** and wait for the numbers to scroll from 0 to 9.
 - If the pump alarms ERROR 02, silence the alarm. ERROR 02 stays on the display. Press **S** to clear the display. Go to step 4.
 - If the pump alarms ERROR 07, or ERROR 03, remove the battery, go to step 5.
4. → Reinsert the battery in compartment 2 (motor). Be sure that it is tight. Tight means that the top of the battery is level with the pump case. Do not over tighten. Set the clock and review the basal rates. Change the pump to RUN.
 - If the pump alarms ERROR 07, remove both batteries and go to step 5.

5. → Press **S** and hold for 3 seconds. Insert a NEW battery in compartment 3 (electronic). Press **S** and wait for the numbers to scroll from 0 to 9.
 - If the pump alarms ERROR 02, silence the alarm. ERROR 02 stays on the display. Press **S** to clear the display. Go to step 6.
 - If the pump alarms ERROR 07, remove the battery and go to step 7.
6. → Insert a NEW battery in compartment 2 (motor). Set the clock, review the basal rates, change the pump to RUN.
 - If the pump alarms ERROR 07, remove both batteries and go to step 7.
7. → Change to your back-up insulin delivery device or contact your health care team for an alternate insulin therapy plan. Call Disetronic at 1 (800) 688 4578.

Note: When both batteries have been removed and then reinserted, the insulin remaining counter is reset to 315.0 units, as if a full cartridge is being used.

If, however, the cartridge is not full, the insulin remaining counter will not reflect the actual amount being used in the cartridge. In this case, you must be ready to change the cartridge at, or before, the usual time.

Also note that the data memory is reset when the batteries are reinserted or replaced simultaneously. For more information see section 3.2.2 "remove both batteries".

7.8 Alarm ERROR 8x: Technical Inspection Alert



("X" stands for the number of weeks until technical inspection is due. The number varies as outlined below).

Technical Inspection is required after the first 24 months of pump use. The pump alerts you when it nears the time for the technical inspection to allow you to schedule the inspection and to change to your back-up insulin delivery device. The pump alarms eight, six, four, and two weeks before technical inspection is due, to allow you to schedule the inspection.

- ERROR 88: 8 weeks before the technical inspection is due
- ERROR 86: 6 weeks before the technical inspection is due
- ERROR 84: 4 weeks before the technical inspection is due
- ERROR 82: 2 weeks before the technical inspection is due

When the pump alarms with a "technical inspection alert" ERROR code, it stays in RUN and beeps continuously.

Do the following:

1. → Press **S** and hold for three seconds to silence alarm. ERROR 8x stays on the display.
2. → Press **S** to clear the display
3. → Call Disetronic at 1 (800) 688 4578, to receive instructions on how to return the pump for technical inspection.

7.9 Alarm ERROR 09: Technical Inspection Due



After 24 months of use (with batteries inserted in the pump), the pump alarms ERROR 09 and beeps continuously. It changes to STOP.

The pump's computer counts the time the pump is used before the technical inspection is due. When the batteries are removed, the pump does not monitor time.

Do the following:

1. → Press **S** and hold for three seconds to silence alarm. ERROR 09 stays on the display.
2. → Change to your back up insulin delivery device.
3. → Call Disetronic at 1 (800) 688 4578, to receive instructions on how to return the pump for technical inspection.

7.10 Alarm ERROR 10: Cartridge Low Warning

When only 20 units (standard setting, see section 2.4) remain in the cartridge, the pump alarms ERROR 10. The pump beeps continuously to warn you that the cartridge is almost empty.

Do the following:



- ➔ If the pump alarms ERROR 10 during basal delivery, the pump beeps continuously and displays RUN.
 - Press any button to silence the alarm (ERROR 10 stays on the display).
 - Press **S** to clear the ERROR-display and to determine the insulin remaining.
 - Change the cartridge before it is empty.
- ➔ If the pump alarms ERROR 10 during bolus delivery, the pump beeps continuously and displays RUN. You may silence the alarm immediately, or wait to silence the alarm after the bolus.

If you want to silence the alarm immediately:

- Press any button to silence the alarm (ERROR 10 stays on the display).
- Press **S** and the "insulin remaining" will continue to decrease on the display for 8 seconds, then the display switches to show the bolus amount. The bolus amount continues to decrease on the display.
- Change the cartridge before it is empty.

If you want to silence the alarm after the bolus:

- Press any button to silence the alarm (ERROR 10 stays on the display).
- Press **S** to clear the display and to determine the insulin remaining.
- Change the cartridge before it is empty.

- ➔ If the volume of insulin in the cartridge reaches "twenty units remaining" while priming, the pump continues the prime. When the prime is complete, the display shows ERROR 10, beeps



continuously, and displays STOP.

- Press any button to silence the alarm (ERROR 10 stays on the display).
- Change the cartridge immediately, or change to RUN and change the cartridge before it is empty.

7.11 Alarm ERROR 11: End of Temporary Basal Rate

The pump alarms ERROR 11 and beeps continuously when a temporary basal rate change, increase or decrease, has ended or has been canceled.



- ➔ If the change has ended, the pump alarms ERROR 11 and displays RUN.
 - Press any button to silence the alarm, ERROR 11 stays on the display.
 - Press **S** to clear the ERROR-display.



- ➔ If the change has been canceled, the pump alarms ERROR 11 and displays STOP.
 - Press **S** to silence the alarm, ERROR 11 stays on the display.
 - Change to RUN.

This section includes:

- 8.1 Blank display**
- 8.2 Incomplete full segment display (insert batteries)**
- 8.3 Incomplete start-up self-check**
- 8.4 Therapy situations**

8.1 Blank display

When the pump is in RUN or STOP, the display will be blank after 30 seconds in order to save battery power.

To illuminate the display:

- 1) Press **h** and **m** at the same time (this is the safest way). Any other button can also be pressed, but then not only is the display illuminated, but the function related to this button will also be activated.

If the display is not illuminated then do the following:

- 2) Reinsert the batteries according to section 3.1 "insert and change batteries."

If the display illuminates then:

- set the clock. (See section 3.3)
- check the basal rate program. (See section 3.5)
- change the pump to RUN. (See section 5.1)

If the pump alarms an ERROR 07 or 03 then:

- insert a new battery in compartment 3 (electronic) according chapter 3.1 "insert and change batteries."

If the display illuminates then:

- insert a new battery in compartment 2 (motor) according to section 3.1 "insert and change batteries."
- set the clock. (See section 3.3)
- check the basal rate program. (See section 3.5)
- change the pump to RUN. (See section 5.1)

If the pump alarms an ERROR 07 or 03 again and/or the display does not illuminate, then change to your back-up insulin delivery device. Call Disetronic at 1 (800) 688 4578.

8.2 Incomplete full segment display (insert batteries)

Insert a battery according to section 3.1 "insert and change batteries."

If the segment display is incomplete after inserting the first battery into the compartment 3 (electronic) then:

- remove the battery
- press **S** and hold for three seconds
- insert a NEW battery according to the instructions in chapter 3.1 "insert batteries."



Caution: For preventing water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.

The full segment display illuminates.

If not, then change to your back-up insulin delivery device.

Call Disetronic at 1 (800) 688 4578.

8.3 Incomplete start-up self-check

The pump performs a self-check when:

- the pump is started for the first time
- both batteries are removed and reinserted or replaced
- the pump is "reset for a new cartridge"

If the pump fails a start-up self-check, then:

1. → remove both batteries
2. → press **S** and hold for three seconds
3. → insert a battery in compartment 3 (electronic).
 - if the display illuminates, go to step 4.

- if the display does not illuminate, remove the battery, go to step 5.
- 4. → Press **S** and wait for the numbers to scroll from 0 to 9.
 - if the pump alarms ERROR 02, silence alarm. "ERROR 02" stays on the display. Press **S** to clear the display. The self-check is complete. Continue with programming.
 - if the pump alarms ERROR 07, ERROR 03, or if the display "freezes", remove the battery, go to step 5.
- 5. → Press **S** and hold for three seconds. Insert NEW battery in compartment 3 (electronic) according to section 3.1.
 - if the pump alarms ERROR 02, silence the alarm, self-check is complete. Continue with programming.
 - if the pump alarms ERROR 07, ERROR 03, or if the display "freezes," remove the battery. Got to step 6.
- 6. → Change to your back-up insulin delivery device.
Call Disetronic at 1 (800) 688 4578.



Caution: For preventing water from entering the pump case:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.

8.4. Therapy situations



Caution: Do not use these procedures without approval of your health care team. Always follow your health care team's recommendations.

This section describes some potential situations and some possible solutions occasionally reported by insulin pump users. These categories include:

- High blood glucose values (Hyperglycemia)
- Low blood glucose values (Hypoglycemia)

These are only suggestions, always check with your health care team.

Troubleshooting high blood glucose (hyperglycemia)

Insulin Causes	Suggested Actions
Poor absorption	Choose infusion sites without scar tissue, bruises, or tissue buildup. Do not use any infusion set/site longer than recommended.
Mismatch of insulin with food	Check pump memory for bolus amount and re-evaluate. Consult health care team for adjustment of insulin-to-carbohydrate ratio, if necessary.
Forgotten meal bolus or bolus taken too long after a meal	Check pump memory to confirm missing bolus. Time the meal bolus according to the onset of insulin action or according to your health care team's recommendations.
Ineffective or expired insulin	Check expiration date of insulin. Do not store vial or filled cartridge where it could freeze or over-heat. Short acting insulin should appear clear upon inspection. Change to new bottle of insulin. Consider half-filling cartridge.

Troubleshooting high blood glucose (hyperglycemia) → continued

Pump/Infusion set causes	Suggested Action
Large air bubbles in cartridge or tubing	Disconnect and prime infusion set to remove air or replace cartridge and re-prime. Make sure all connections are secure.
Blood in tubing	Change infusion set and site.
Empty or reused cartridge	Replace cartridge. Cartridges are for single use only. Do not reuse.
Disconnected or dislodged infusion set	Tug on connections to check security. Check for wetness due to leaking insulin. Check blood glucose level.
Leak in system	Look and feel for wetness due to leaking insulin at all connections and on the skin.
Blockage in system	Change infusion set, site, cartridge. Check piston rod and change if necessary.
Incorrect clock setting	The correct hourly basal rate may not be delivered if the time is incorrect. Check the clock on regular basis and when replacing battery (s).
Failure to complete prime	Always prime until insulin drips from the end of the tubing and the tubing is free of air.
Pump in stop for extended period	Consult health care team for allowable time off the pump and for an off-pump injection regimen.
Incorrect pump programming or basal rates not matched with needs	Always review any changes made in basal rate programming. Check with health care team about possible rate adjustment.

Troubleshooting high blood glucose (hyperglycemia) → continued

Other Causes	Suggested Action
Decreased activity, illness or stress	Check with health care team about using temporary basal rate increase.
Additional medication other than insulin	Some medications other than insulin may affect blood glucose. Check with your pharmacist or doctor if your medications may have this effect and ask how to adjust rates accordingly.
Rebound from low BG or Dawn phenomenon (rise in glucose in early morning hours)	Consult health care team to re-evaluate blood glucose control and overnight pump settings.

Troubleshooting low blood glucose (hypoglycemia)

Insulin Causes	Suggested Action
Bolus dose too high for amount of food eaten	Check pump memory for amount given and re-evaluate; also may need to consult health care team to adjust insulin-to-carbohydrate ratio.
Alcohol consumption	Be sure to eat when consuming alcohol; increase blood glucose monitoring, as hypoglycemia may occur much later.
Basal rates too high	Call health care team for basal adjustment if cannot skip a meal without hypoglycemia.
Temporary basal rate too high	Re-evaluate percentage of basal adjustment for the level of activity. Consult health care team.
Increased absorption Do not wear the pump in hot tubs, saunas, baths, showers, or when swimming.	Hot tubs, saunas, long hot baths, or exercising a limb where an infusion site is located all may cause an increase in insulin absorption. Make adjustments for this or avoid these activities.

Troubleshooting low blood glucose (hypoglycemia) → continued

Pump/Infusion set causes	Suggested action
Incorrect pump programming or basal rates not matched with needs	Make sure to review basal rate changes after they are made. Check with your health care team about possible rate adjustment.
Incorrect clock setting	The correct basal rate for a time period may not be delivered if the clock is not set correctly. Check the clock on a regular basis and whenever battery(s) are replaced.
Priming the infusion set while it is inserted in the body	Priming will automatically deliver 25 units of insulin from the cartridge. Never prime with infusion set connected to your body; you risk unintended delivery of insulin.
Disconnecting infusion set from luer lock end while set is inserted in the body	When changing the cartridge or infusion set, disconnect at the site; disconnecting at the luer (adapter) end may cause unintended delivery of insulin.

Other Causes	Suggested Action
Increased physical activity	Most people need less insulin when more active. Check with your health care team about reducing insulin for increased activity using the temporary basal rate decrease.
Medication other than insulin	Some medications other than insulin may affect blood glucose. Check with your pharmacist or doctor if your medications may have this effect and ask how to adjust rates accordingly.

This section includes

9.1 Recommendations for daily use

9.2 Interruption of pump therapy

9.3 Use of a partially filled cartridge (plastic cartridges only)

9.1 Recommendations for daily use

Training and use of the pump requires support of an experienced trainer and health care team. Regular visits with your health care team are absolutely essential in pump therapy. Always follow **the instructions given by your health care team**. Only change your personal settings after consulting your health care team.

Successful pump therapy requires frequent self-monitoring of blood glucose values, at least 4 times a day, or as directed by your health care team.

Traveling

Ask your health care team about any special precautions needed prior to your trip. Make sure you bring extra supplies. Also make sure you know places where you can obtain supplies should this become necessary.

9.2 Interruption of pump therapy

Consult your health care team about when and for how long insulin pump therapy can be interrupted, for example to go into a sauna, during sport activities with hard body contact or swimming.

Short interruption

1. Change the pump to STOP.
2. Completely remove the infusion set and close the cartridge with a protective cap. Or, using a disconnectable infusion set, disconnect at the site and put the protective covers on the connectors.
3. Silence the STOP-Alarm (refer to section 6.4 "control the STOP-Alarm").

Measure your blood glucose value regularly during the interruption. Inject insulin according to the instructions of your health care team with a syringe or insulin pen.

Continuation of the therapy

1. Attach a new infusion set and prime it prior to inserting it into your body. Or, for the disconnectable infusion sets, reconnect the tubing to the needle. (There is no need to bolus for air space when re-connecting!)
2. Change to RUN.

Within two hours, measure your blood glucose value in order to check the operation of the system and to ensure insulin delivery.

Interruption of the operation of the pump for a longer period of time



Caution: Contact your health care team for an alternate therapy plan when you will be off the pump for a longer period of time.

Interruption of pump operation for more than one day, for example:

- when storing the pump and using your other pump, if available
 - when wishing not to wear the pump, e.g. during a vacation at the beach to avoid getting sand into the pump or when outside in very hot and sunny climate to avoid overheating the insulin
 - when the pump needs maintenance or repair.
1. Change the pump to STOP.
 2. Remove the cartridge and the infusion set.
 3. Remove both batteries and insert the battery compartment covers.
 4. Connect the adapter to the pump and store the pump according to the right temperature conditions (see section 11 "technical data") or, if necessary, send the pump to Disetronic.

9.3 Use of a partially filled cartridge (plastic cartridges only)



Warning: If the actual amount of insulin in the cartridge does not match the calculated amount of insulin, you may or may not get a "cartridge low warning" ERROR 10 and/or "empty cartridge" ERROR 01. If neither ERROR 10 nor ERROR 01 alerts you about the necessity of a cartridge change, then ERROR 04 (occlusion) will alarm to indicate the cartridge is empty. Proceed as indicated for ERROR 04 (see chapter 7.4 "Alarm ERROR 04: occlusion").

A half-filled plastic cartridge may be used in the pump. To accurately half-fill a cartridge with 150 units, the top of the plunger must be positioned between the 140 and 160 marker lines. Once the cartridge is half-filled, the pump must be "reset for a new half-filled cartridge," see section 4.4.2 "reset new half-full plastic cartridge."

Any partially filled cartridge should be filled accurately, so that its actual volume matches the calculated "reset volume" for a half-filled cartridge.

This section includes:

10.1 Repair and technical inspection

10.2 Maintenance and cleaning

10.2.1 System check

10.2.2 Insulin pump

10.2.3 Piston rod

10.2.4 Pump adapter

10.2.5 Cartridge and infusion set

10.3 Store the pump

10.4 Battery information

10.5 Your pump checklist

10.6 Package and return the pump

Disetronic Medical Systems AG as manufacturer guarantees the functions of the H-TRONplus Insulin Pump according to the specifications, on condition that all the servicing of the H-TRONplus is done by Disetronic or a Technical Service Center authorized by Disetronic.

The pump has no scheduled maintenance during the operating time.

Do not do any servicing or repair on the pump by yourself.

10.1 Repair and technical inspection

Return the pump to Disetronic in the following situations:

- For any technical inspection
- In case of troubles such as an ERROR can not be cleared by following the procedure described in section 7.
- After the first 24 months of use, a pump must be returned for a **"technical inspection."** The pump alerts you when the time for the technical inspection nears, which allows you to change to your back-up insulin delivery device. The pump alarms "technical inspection" (ERROR 88) eight weeks before the inspection is due, and then again at two week intervals. When the pump has been in use for a total of 24 months, it changes to STOP and alarms "technical inspection due" ERROR 09.

Schedule the technical inspection with Disetronic Technical Service.

Technical Service

Disetronic Medical Systems, Inc.

5151 Program Avenue

St. Paul, MN 55112-1014, USA

Phone 1 800 688 4578

The 24 months of use is calculated by the pump, based on the length of time that the batteries are in the pump. The time when the batteries are removed is not counted.

10.2 Maintenance and cleaning

For best operation of the pump pay attention to the following items:

10.2.1 System check

Only a well maintained system guarantees an accurate dose of insulin.

Check the insulin pump, the cartridge, the adapter, the infusion set and the infusion site regularly. Replace and discard these items according to the instructions of your health care team and according to the specifications in the corresponding user instructions. Use only specified accessories and disposables!

10.2.2 Insulin pump

Inspect the pump case daily for cracks or chips. Check the blue button covers and the S-button for damage. Be sure that the buttons rebound when pressed.

Check the display window for any cracks or blank spots that would indicate poor condition.

If the insulin pump had contact with water then immediately dry it well with a soft dry cloth.



Caution: Do not clean with water! Do not use any solvents or strong detergents for cleaning and avoid any contact of the case with perfumes or deodorants.

Use only a soft dry cloth to clean the pump and the cartridge compartment, for example if insulin leaked into the compartment. If the compartment is too dirty to be cleaned with a dry cloth, then send the pump to Disetronic Technical Service for cleaning.

Send your pump to Disetronic Technical Service for a technical inspection when it is scheduled.

10.2.3 Piston rod

The piston rod moves the plunger forward in the cartridge. Ensure that the cog wheel spins freely on the piston rod. The nylon end cap should spin freely and the metal rod should be clean.

Replace the piston rod:

- when worn
- when the nylon end cap becomes loose, broken or does not spin
- when the cog wheel does not spin freely and
- yearly.

A dirty piston rod, for example with crystallized insulin on it, may cause an "occlusion alarm" ERROR 04.

10.2.4 Pump adapter

The pump adapter provides a reliable connection between the pump, cartridge and the infusion set. Inspect the "O"-rings before putting the pump adapter on the pump. They should not show signs of wear. The two small openings on the adapter allows air pressure to equalize. Keep them open and clean.

Replace the pump adapter:

- when the "O"-rings are worn, damaged or missing
- when the openings are blocked and
- after 6 months of use.

10.2.5 Cartridge and infusion set



Caution: The cartridge and the infusion set are sterile products and only for single use.

Replace and discard these items according the instructions of your health care team and according the specifications in the corresponding instructions for use.

10.3 Store the pump

When the pump will not be used for a long time, it must be properly stored. To store the pump:

- remove both batteries. Removing the batteries turns the pump off, so the internal clock that monitors the time the pump is used is also turned off.
- replace the battery compartment covers and the pump adapter
- store the pump in its original case.

Storage conditions

Temperature	-40 to +149°F (-40 to +65°C)
Air humidity	10 to 100 %
Barometric pressure	500 to 1060 mbar

10.4 Battery information



Caution: For preventing water from entering the housing:

- Change pump batteries only in a dry environment.
- When changing a battery, check that the black "O"-ring is correctly installed and seated properly.



Caution: Removing both batteries simultaneously will cause the data memory to be erased (including current settings such as temporary basal rate changes or programmed bolus), the loss of the remaining cartridge volume, the history of alarms ERROR 10 and ERROR 01 and the time setting. Reinsert the batteries according to section 3.1.1 "insert the batteries" after having removed them simultaneously. You need to reprogram/verify all pump settings and start with a new cartridge. If not, your insulin remaining counter will not match the actual contents of your cartridge.



Caution: Do not try to recharge the battery. Do not open the battery or dispose of it in a fire.

Always have **extra** batteries available and pay attention to the following.

- Do not store the batteries in the refrigerator or freezer. High humidity affects battery life.
To store the batteries respect the following conditions:
Temperature +32 to +86°F (+0 to +30°C)
Air humidity 10 to 80%
- Prevent early discharge of the batteries by preventing contact between the batteries themselves and between the batteries and any other metal. Always keep batteries in the original package until ready to use.
- For operating the pump, the temperature of the batteries must be +41°F to +122°F (+5°C to +50°C).
- To tighten batteries use only the Disetronic battery tool until the top of the battery is level with the pump case. Over tightening may cause damage to the pump housing.
- Use only Disetronic batteries. If not, the settings and alarms may be incorrect and/or the pump may be damaged.

The working life of the batteries (2 and 3) is affected by usage of the pump, rates, temperatures, etc. Batteries should last approximately 4 weeks or more.

Testing batteries

1. Remove both batteries from the pump. Put the battery to be tested in compartment 3 (electronic) according to section 3.1 "insert and change batteries". Leave the compartment 2 (motor) empty. If the

display does not illuminate, discard the battery. If the display illuminates, then

2. Press **h** or **m**. The display should scroll through the self-check numbers 0 to 9. If not, discard the battery. If the battery passes the self-check, then
3. The pump will show an alarm. If the pump alarms "low electronic battery" ERROR 03, discard the battery. If the pump alarms "low motor battery" ERROR 02, silence the alarm and keep the battery.

10.5 Your pump checklist

Check your insulin pump at least daily. Make sure that:

- the batteries are inserted properly, so that the top of the battery is level with the pump case.
- the basal rates are set correctly, according to your health care team's recommendation.
- the clock is accurately set.
- the piston rod is properly inserted.
- the cartridge and infusion set are free of air bubbles.
- the pump adapter is tight.
- visually inspect the cartridge and compare the actual amount of insulin to the calculated amount on the insulin remaining counter.
- the infusion set is primed, free of air bubbles, and is tight on the pump adapter.
- the infusion set is inserted according to manufacturer's instructions.
- the pump is in RUN.
- the infusion site is secure, comfortable and free of irritation.
- the pump case is free of chips or cracks, buttons are free of tears or slits, display is free of cracks or incomplete characters.
- the temporary basal rate changes are set or planned according to your health care team's recommendations.
- the emergency kit or travel kit with supplies is available when needed.
- the back-up pump, or alternate insulin delivery method is available when traveling.
- the beeps are turned on or off as desired.

10.6 Package and return the pump

A pump may be returned to Disetronic Technical Service when approved. Pack the pump so it can travel safely. For example, put the pump back in the original carrying case and put the case in a package that will not rip or tear.

It is best to send the pump by a carrier that tracks the shipment. Some examples of tracked shipments are:

- Federal Express 2-day economy
- UPS ground track
- registered mail
- express mail
- certified mail

Remember to include a note with:

- the return number provided by Disetronic
- a description of the reason for returning the pump
- your name and address
- your daytime phone
- the serial number of your pump

If your pump is not covered under your homeowners' insurance policy, you may want to insure it with the shipper for its full value.

Your pump should be returned to:

Technical Service

Disetronic Medical Systems, Inc.

5151 Program Avenue


















St. Paul, MN 55112-1014, USA











Phone 1 800 688 4578

11.1 Technical data

Dimensions (l x d x h)	84 x 54 x 19 mm
Weight	< 100g (batteries included)
Case	Plastic (Polycarbonate), all edges rounded
Temperature ranges	Operating +41 to +122°F (+5 to +50°C)
	Transport/storage -40 to +149°F (-40 to +65°C)
Air humidity	Operating 10 to 90 %
	Transport/storage 10 to 100%
Barometric pressure	Operating 700 to 1060 mbar
	Transport/storage 50 to 1060 mbar
Connections	serial interface only for servicing
Power supply	two 3 volt silver oxide proprietary batteries
Safety system	2 micro processors, alarms with automatic STOP
Switch-off pressure	max. 4×10^5 Pascal (4 bar)
Dosage of the insulin	
– Basal rate	1/20 th of basal rate every 3 minutes
– Bolus and priming the infusion set	Continuously with a rate of 9 U./minute \pm 20% (U-100)
Accuracy of the dosing	
– Bolus	at min. bolus (0.5 U.) < \pm 0.1 U. at max. bolus (25 U.) < \pm 0.3 U.
– Basal rate	at 10 U./h < \pm 5%
Occlusion bolus volume	\leq 4.5 U. plastic cartridge
	\leq 10 U. glass cartridge

11.2 List of symbols

	Read instructions for use
	Sterilized with ethylene oxide
	Sterilized with radiation
	Sterilized with antiseptic
	Date of manufacture
	Batch number
	Expiration date
	Item number
	Serial number
	Permissible temperature range
	Permissible humidity range
	Permissible air pressure range
	Fragile – handle with care
	Protect against moisture
	Protect from heat and sunlight
	For single use only
	Does not contain pyrogen

	Does not contain PVC
	Recycling
	Do not throw away
	Flammable
	See
	Apparatus type BF according to standard EN 60601-1. (Protection against electrical shock)
	Pump case protects the pump against the effects of temporary immersion in water according to the standard IEC 60529.
	CE mark according to European Medical Device Directive
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Sticky tape

Basal rate

The continuous rate of insulin that is delivered in units per hour. The basal rate provides coverage over a 24-hour period of time. In the H-TRONplus this can be programmed independently for each hour of a 24-hour period.

Basal rate decrease

A temporary decrease in the programmed basal rate that can be programmed by the pump user.

Basal rate increase

A temporary increase in the programmed basal rate that can be programmed by the pump user.

Basal rate total

The total amount of insulin delivered by the basal rate over 24 hours.

Battery compartment

Opening in the pump for the motor battery (2) and the electronic battery (3).

Bolus

The amount of insulin delivered at one time to cover food, or elevated blood glucose value, or other special needs.

Cartridge

An insulin reservoir designed to be used in the insulin pump.

Cartridge compartment

The opening in the pump for the cartridge.

Cog wheel

The nylon wheel on the piston rod.

Display (LCD - Liquid Crystal Display)

The visual display on the insulin pump. Programming information appears in the display.

Dual microprocessors

The computerized electronic components that control the operation of the pump.

Infusion set

The connector, consisting of a luer-lock connector, tubing, and needle that carries insulin from the pump cartridge to the insulin pump user's body.

Infusion site

The place where the infusion set needle is inserted in the skin to deliver insulin.

Luer connector (luer-lock)

A fitting at the end of the infusion set and on the cartridge which allows them to be locked together without leaking.

Multiple basal rates

More than one basal rate delivered within a 24-hour period. Up to 24 hourly rates may be programmed with the H-TRONplus Insulin Pump. The rates are changed at time intervals set by the insulin pump user.

Nylon end cap

The portion of the piston rod that fits into the plunger inside the cartridge. The nylon end cap pushes the cartridge plunger when the piston rod is rotated by the motor.

Profile

A basal rate profile consists of 24 hourly basal rates. Usually unique for each insulin pump user.

Pump adapter

A cylindrical object that screws into the cartridge compartment to hold the cartridge in place. An infusion set is screwed into the pump adapter. The adapter has two holes for air pressure compensation.

Reset

A process that resets the insulin remaining counter for a new full or half-full cartridge.

Status (operating status)

A condition of insulin pump operation, either RUN, when insulin is being delivered, or STOP, when insulin is not being delivered.

Subcutaneous

A term that means "beneath the skin." The infusion set needle is inserted subcutaneously.

Temporary basal rate

The programmed basal rate can be temporarily increased or decreased to adjust insulin for special situations, such as for changes in activity or illness that may require more or less insulin. The pump automatically returns to deliver the programmed rate after a specified time.

Total amount of insulin delivered since midnight

An information display (data memory) that indicates the total amount of insulin delivered since midnight. The total includes all basal rate delivery, all boluses and any temporary basal rate changes that have occurred. This amount does not include any volume from the prime function.

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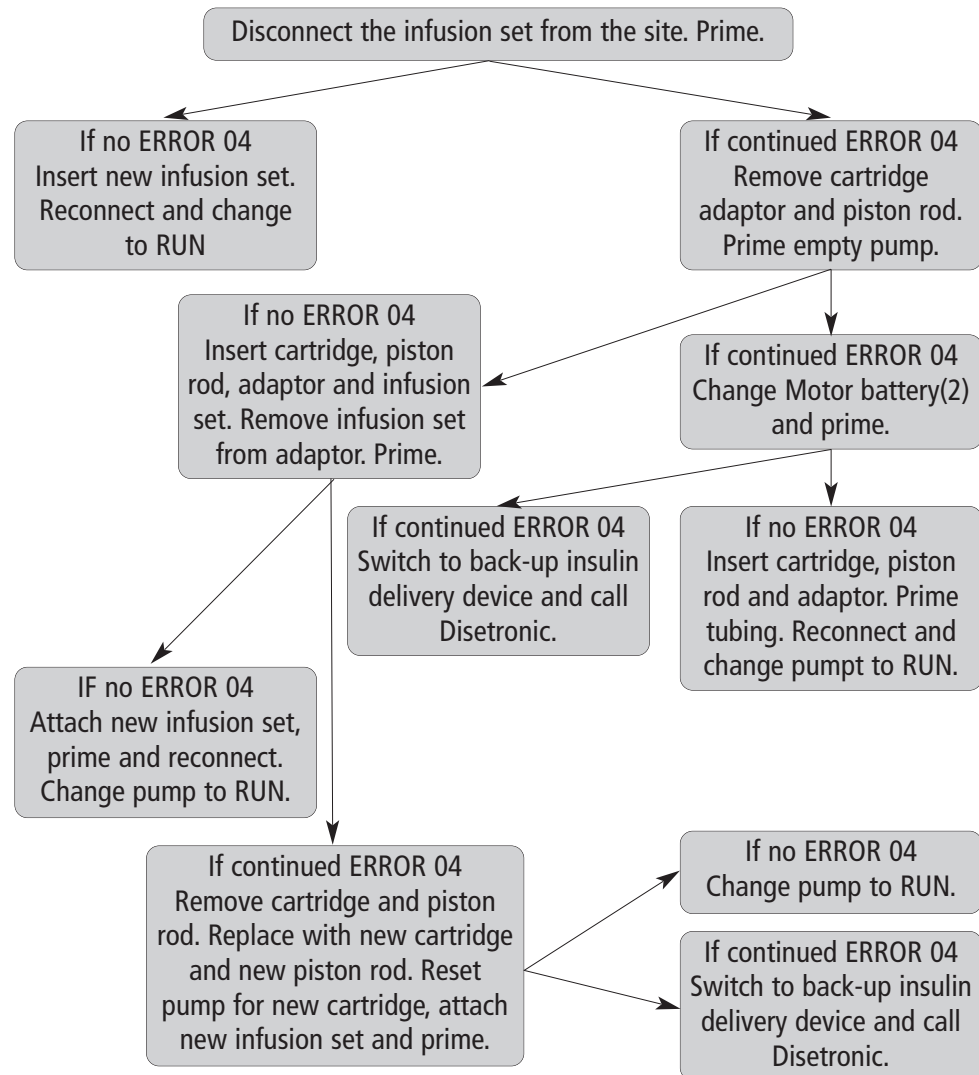
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With a disconnect infusion set do the following:

1. → Press **S** and hold for three seconds to silence the alarm, ERROR 04 stays on the display.
2. → Check blood glucose. If elevated, treat according to your health care team's instructions. Then:



Operating the H-TRONplus

Quick programming reference

Insert/remove the batteries

activates the "time to technical inspection" counter

Activate the display

h **m** for one second

Silence and clear an ERROR

S to silence: press **S** until a long beep sounds

S to clear from display: press **S** briefly

Legend

Press button once

Press button several times

Press button Press button together

Press the buttons within 8 seconds, otherwise the pump will quit the selected function and return to the preceding function or the actual status.

